FADONA/LTC
Preconvention
MARCH 2023

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Florida Association Directors of Nursing Administration/LTC

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NADONALTC
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FADONA is a state chapter of NADONA, (800) 222-0539.

Message from the President

Carrying the Torch of Leadership's 36th Annual Convention & Trade show is fast approaching — March 20-23, 2023, at the Rosen Plaza Hotel in Orlando. It's still not too late to register online at **www.fadona.org**.

Susie Jensvold

Our thanks go to Betty Baron, 1st Vice President & Convention Planning Chair, who worked with the planning committee to create an exceptional event to assist post-acute and long-term care (PALTC) nurse administrators in leading their organizations in quality resident care and quality of life.

We are presenting an amazing Preconvention Day on Monday, March 20. Debbie Afasano, RN, BSN, CDONA, HCRM, LNC, CSA, will be presenting a 6-hour workshop, *Sparketype® "Discover Your Unique Imprint."*

We all have a certain "imprint" for work that makes us come alive. Work that lets us wake up in the morning and know, deep down, we're doing what we're here to do. Work that sets us ablaze with purpose, and fully expressed in a healthy way, becomes a mainline to meaning, a pathway to that transcendent state of flow, and a gateway to connection and joy. Put another way, work that "sparks" us. We call this imprint or identity your "Sparketype®."

Once you discover this, there is an intuitive knowing and an undeniable truth that explains so many past choices and outcomes – and empowers you to contribute to the world on a very different level.

Don't miss this incredible opportunity to be inspired!

The wide range of convention topics includes clinical, regulatory, legal, and administrative, including two inspirational keynote presentations, and as always, AHCA's Regulatory Update with Dep. Sec. Kim Smoak, to name a few.

FADONA/LTC is the premier organization for directors of nursing and nurse administrators in the state of Florida.

Come join the fun and education to enhance the quality of patient care at our centers. You will have the opportunity to network and share ideas with your peers.

A Mission Impossible Fun Night with our Alliance Council's Platinum Partner vendors will be filled with Fun. It will feature casino tables, DJ and dance floor, karaoke, and fabulous prizes for the Chinese Auction.

We are all confronted with our facility's challenges and face new ones daily. The pandemic has been a case study in resiliency. As the complexity of health care as a field and our residents continues to evolve, so must we as a profession — with the ultimate charge of protecting our residents and colleagues.

Come join us for education, fun, laughter, and camaraderie with your FADIONA fanily at the Rosen Plaza Hotel!

To survive, we need to support each other. FADONA is where the support can be found. Our focus is to provide education and influence throughout the state. Help us create a larger and louder voice for our residents.

Mark your calendars, and plan to attend. We must all know how to navigate the regulations, standards of practice, and techniques in order to help our nursing staff stay up to date with the best practices.

Members United in the PALTC Continuum

The leadership is passionate about FADONA's place in the continuum and its role in providing members with the necessary tools to allow them to succeed and excel as professionals and as nurse administrators. We continue to have a positive impact on quality care and increase our membership. You can assist by inviting your colleagues to be members if they are not. You may contact your FADONA board members or staff at any time.

Please check out our website at www.fadona.org for additional news and updates.

Respectfully submitted,

Susie Jensvold

Susie Jensvold, BSN, MHSA, RN
President

FADONA's 36th Annual Convention: *Mission Possible*

Convention Corner by Betty Barron, MSN, RN; 1st Vice President, and Chair, Convention Planning Committee, FADONA

It is with great pleasure that I share FADONA's 36th Annual ***Carrying the Torch of Leadership 2023***. This year's theme is Mission Possible.

Betty Barron

Now that we have a "good handle" on COVID, hopefully the challenges of the past three years are behind us. I am grateful that we are coming together for another successful convention. There is nothing better than face-to-face interaction with colleagues and friends as we continue our mission of serving our communities.

Planning this convention, I was excited knowing that we will come together with other LTC leaders nurses from all over Florida. I have been elated to be co-chair this convention with our president, Mme. Susie Jensvold.

I want to thank the FADONA Board and staff for their hard work to turn our initial visions for this conference into reality. The 4-day event includes multiple informative sessions. The preconvention session provides a unique, informative, and interesting workshop to empower our nurse leaders with the tools and resources to not only gain insight and knowledge about their own Sparktype® but how knowing others Sparktype® can help align their management team for great success. So, make sure you attend this workshop to "Discover Your Unique Imprint"

Conventioneers will have plenty of opportunities to connect with peers, meet FADONA members, share best practices, survey and regulatory updates, and get a glimpse of the latest innovations from exhibitors to aid in providing optimal patient care.

We are thankful to our sponsors, members, speakers, and supporters who continue to contribute to FADONA's work. Without their generous support, this convention would not be possible.

The Awards Luncheon is on Wednesday. This is when we salute Florida's best and brightest in an uplifting and inspiring event. Special congratulations to our award recipients. A special thanks to Optum for supporting our Nurse Administrator of the Year Award for 20 years; RB Health Partners for supporting the LPN & CNA Awards of Excellence for 13 years; and Guardian for sponsoring the hotel key cards for 12 years. Amazing!

Thank you to all those who donate to the Patches Bryant Scholarship supporting the education of our LTC nurses. Make sure you look for the Themed Basket Auction in the exhibit hall. Proceeds for the baskets go to the scholarship fund.

Fun Night is sponsored by our Alliance Council. It is full of fun, laughs, and good times. This year we will setting off on a mission with casino tables, a photo booth, karaoke, and more. So come ready to PARTY.

By working together, we have become a cohesive force through which we produce positive changes in our industry. Networking at meetings like this is vital and ultimately benefits the residents of our facilities. ◆

Quotable Quotes from FADONA's 35th Annual Convention Carrying the Torch of Leadership 2022

FADONA is a wonderful organization and for the past 17 years I have looked forward to the convention. Thank you.
– Kathleen Jean-Louis, RN; West Palm Beach, FL

It's simply great.
– Chantelle Kocik, RVP; Pompano Beach, FL

Fun night was great!! A real "let down your hair and have fun" setting. Great prizes even though I did not win any. The no pressure product theatre had lots of info and networking also.
– Shalves Anderson; RN; Apopka, FL

Great conference! Loved the fun night and trade show. All around great experience.
– Lori Overstreet, PhD, MSN, RN-BC; Jacksonville, FL

Great information! So informative! Keep up the GREAT work. Thank you!
– Susan Turner, RN; Cocoa, FL

Fun night was epic. Love it, always fun.
– Betty Barron, MSN, RN; Spring Hill, FL

Thank you again for another excellent convention!
– Deborah Grotke, RN; Lake Worth, FL

The venue was absolutely fantastic. Great banquet staff. The FADONA support staff was also fantastic.
– Ghislaine LeDuc, RN; Largo, FL

Great info for the DONs.
– Amina Dubuisson, DNP, MSN, MBA/HCM, RN, LNHA, CDP; Miramar, FL

Amazing, very interactive.
– Jannet Zephyr, RN; Miami, FL

Wow, learned so much. I have attended state and national of your variety of education, the welcome received was above and beyond what I expected. Thank you.
– Betty Brunner, RN, NHA, FACDONA; The Villages, FL

All good, great info, on target.
– Angela Smith, RN; Pembroke Pines, FL

First time attending but enjoyed immensely! Lots of information for me to take back to use at my facility.
– Lori Overstreet, PhD, MSN, RN-BC; Jacksonville, FL

It was a well-planned and well-organized convention. A lot of knowledge was spread around and networking was amazing. Keep up the great work! Look forward to the next time we meet!
– Susan Turner, RN; Cocoa, FL

It was an amazing experience.
– Ashley Lanier, Rockledge, FL

It was my first convention and I enjoyed it. Thank you.
– Sylvie Trudel, RN, CWCMS; Cape Coral, FL

Overall great conference, awesome fun night! Can't wait until next year!
– Coeleen Bender, RN; Inverness, FL

This was my first FADONA conference and I was very impressed with the entire conference. Looking forward to going to this annually.
– Jeanne Tracy, RN; Ormond Beach, FL

Was an amazing week... can't wait until next year ;)
– Liz Borer, RN; North Point, FL

So Many Reasons to Register Today!

Recharge ❖ Refresh ❖ Rejuvenate ❖ Invigorate ❖ Innovate

Sign up today for the most innovative lineup of clinical, administrative, and motivational offerings!

— The BEST QUALITY NURSE LEADERSHIP EDUCATIONAL VALUE in Florida —

- **Must-Attend Preconvention Intensive** — SPARKETYPE® "Discover Your Unique Imprint" – Learn the Work that Makes You Come Alive.
- **Welcome Reception** — 5:35-7 p.m., Monday, March 20 — Sponsored by Avante Group
- **Expert Speakers** — State-of-the-art presentations by expert nurses, regulators, consultants, physicians, and pharmacists who understand and appreciate LTC.
- **90-Minute Update from the Agency for Health Care Administration** — Need-to-Know Regulatory Update
- **Awards Presentations** — Help us honor the best Florida CNAs, LPNs, and Nurse Administrators in long-term care.
- **Fun Night** — Enjoy an evening with great food, super entertainment, dancing, Chinese auction door prizes, and fun with your friends, colleagues, and vendors.
- **SAVE MONEY with Flexible Options & Affordable Fees** — Discounted early-bird registration fees
- **Amazing Wednesday** — **March 22, 2023!**
  - Includes all educational sessions on March 22; CEs/CEUs; Awards Recognition; Trade Show pass – ***ONLY $175***
  - Special rate for additional staff members from the same facility, organization, or corporation – ***ONLY $150***
- **CEs/CEUs** — **Earn up to 22.0 CEs/CEUs** for Florida licensed nurses and Florida licensed nursing home administrators.
- **Hotel Reservations** — **Rosen Plaza Hotel, 9700 International Drive, Orlando, FL 32819; www.rosenplaza.com**
  The special FADONA group rate is $165 per night for Standard Resort King or Double Queen, with no resort fee, and 50% discount off self-parking for overnight guests. For hotel reservations, call **(800) 627-8258** or **(407) 996-9700** (hotel direct), and identify yourself as part of the FADONA Convention Group to receive the group rate. You may also reserve online by going to **www.fadona.org/convention.html**.
  - Hotel will provide group rate for three (3) days pre- and three (3) days post-program dates, based on availability.
  - Complimentary high-speed internet access in guestrooms and public spaces with basic wireless internet access in the assigned meeting rooms and pre-function areas. Reservations must be made no later than **Feb. 28, 2023**. Reservations requested after the cut-off date will be on a space-available basis.

Providing critical information for exceptional DONs, ADONs, Nurse Consultants, LTC Nurses, and Administrators!

Visit https://www.fadona.org/convention.html to register today to attend FADONA's 35th Annual Convention: Power of the Past – Force of the Future

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SAVE THE DATE!

March 20-23, 2023

FADONA's 36th Annual Convention

MISSION: POSSIBLE

Optional Preconvention Workshop:
Sparketype® "Discover Your Unique Imprint"
Debbie Afasano, RN, BSN, CDONA, HCRM, LNC, CSA;
President, Carpe Diem HCC; the only Certified Sparketype® Advisor in Florida
Your Sparketype® is your source code for work that makes you come alive.
Register today! This impactful workshop includes: 6 CEUs, lunch, and "Sparked" by Jonathan Fields, www.sparktype.com.
Optional Workshop Fees: **$195** for members and **$245** for non-members
Join today at www.nadona.org and save $50.

Register online and book your hotel rooms for

FADONA's 36th Annual Convention at

http://www.fadona.org/convention.html

For assistance, call Shane at the Business Office, (561) 689-6321.

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Optum® works with skilled nursing facilities to provide an added layer of care for residents in participating health plans. Our advanced practice clinicians provide these long-term residents and their families care that supports aging in place. A study done by Harvard Medical School found that the Optum ISNP model can lower emergency department (ED) and inpatient utilization among nursing home residents. This means a higher quality of care, reduced costs and improved census stability.

38% fewer hospitalizations

51% fewer ER visits

45% fewer re-admissions

112% higher rate of SNF use

We've been helping bring peace of mind to residents and their caregivers for over 30 years. We appreciate your participation in this journey. Together, we can help make the health care system work better.

Let's talk about a partnership in care.

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FADONA's 2023 Annual Convention Sponsorships and Support

***Grand Sponsor**: Urovant*
***Classis Sponsors**: Medline, Optum, Teva, Vitas*
***Patches Bryan Scholarship**: AbleHearts*
***CNA/LPN Awards of Excellence**: RB Health Partners*
***Welcome Reception on Monday**: Avante*
***Tote Bags**: connectRN*
***Breakfast on Thursday**: Omnicare*
***Name Badge Holder**: Aston Health*
***Hotel Key Cards**: Guardian Rx*
***Nurse Administrator Award**: Optum*
***T-Shirts**: Optum*
***Coffee Breaks**: Optum, Sheridan Dental*

FADONA's 36th Annual Convention
Optional Preconvention Workshop

MONDAY, MARCH 20

SPARKETYPE® "Discover Your Unique Imprint"

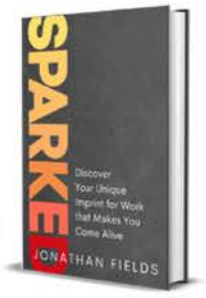
~ **Debbie Afasano, RN, BSN, CDONA, HCRM, LNC, CSA;** President, Carpe Diem HCC – Florida's only Certified Long-Term Care Sparketype® Advisor

Learn how to Spark your life and ignite those around you!

Overview: We all have a certain "imprint" for work that makes us come alive. Work that lets us wake up in the morning and know, deep down, we're doing what we're here to do. Work that sets us ablaze with purpose, and fully expressed in a healthy way, becomes a mainline to meaning, a pathway to that transcendent state of flow, and a gateway to connection and joy. Put another way, work that "sparks" us. We call this imprint or identity your "**Sparketype®**."

Your Sparketype®" is your source code for work that makes you come alive. Once you discover it, there is an immediate, intuitive knowing and an undeniable truth that explains so many past choices and outcomes – and empowers you to contribute to the world on a very different level.

Get ready to spark your life and ignite those around you. The training will provide 6 CEs and will be held from 9 a.m. to 5 p.m. on Monday, March 20, 2023, during FADONA's 36th Annual Convention & Trade Show.



The fees for this exceptional preconvention workshop include lunch and a copy of Sparked by Jonathan Fields.

Get ready to spark your life and ignite those around you. This amazing training provides 6 CEs and will be held from 9 a.m. to 4:30 p.m., including lunch and breaks.

Don't miss this opportunity to be inspired!

Convention News

Continuing Education

This educational program will be approved for **22.0** maximum contact hours for **Florida licensed nurses** and **nursing home administrators** by FADONA, CE Broker Provider #50-682.

"Paperlite" Convention

In keeping with our organization-wide initiative, the convention will be paperlite. This means that we will not be providing printed session handouts.

Handouts will be available online for paid registrants at www.fadona.org. This will allow you to view and print them free before you arrive. Look for the handouts to be posted online **7-10 days prior** to the convention.

However, please be aware that we cannot ensure the availability of every PowerPoint presentation or handout for every session.

Fun Homemade, Themed Gift Basket Contest & Silent Auction

Support the Patches Bryan Scholarship!

We are inviting all our members, convention attendees, and exhibitors to create and donate themed homemade gift baskets for the silent auction in the Exhibit Hall.

All proceeds from the sale of these baskets will benefit the **Patches Bryan Scholarship**. Over the years, FADONA has provided more than **$42,500** in scholarships to its members and their staff and, with your support, we will be able to continue this noble tradition.

Baskets will be judged by a panel of Platinum Partners, and the top three will each receive an Amazon e-gift card **($100, $50, or $25)**.

Judges will be looking for the
***Most Creative**, **Most Number of Bids**,*
*and **Highest Dollar Bid**.*

Our thanks to **Greystone** and **Able Hearts** for their ongoing support as co-sponsors of the **Patches Bryan Scholarship**.

For more information on how you can participate, please call **Shane Bellotti** at the FADONA business office, **(561) 689-6321**.

Thanks for Your Donated Baskets!

Rosen Plaza Hotel, Orlando

Please note that FADONA is financially responsible for all hotel rooms reserved in its group block. Any unused rooms, not sold, are still billed to FADONA in the form of attrition. We ask for your support in booking only at the convention hotel to ensure we fill the room block and can continue to offer discounts to our attendees. We ask that you reserve hotel rooms realistically and cancel any unneeded rooms with as much notice as possible. Thank you for your cooperation. **For hotel reservations, please see the bottom of the registration form on the next page.**

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Properly equip patients or residents, family and staff with everything they need to stop pathogens from spreading through hand, face and bodily contact.

3 Clinical practice
Give caregivers tools that make it easy to reliably follow best practices and keep pathogens from invading the procedure site.

MEDLINE **Infection Prevention**

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Let's Spark

By Debbie Afasano RN, BSN,CDONA, HCRM, LNC, CSA™; President, Carpe Diem Health Care Consulting

I am SPARKED™ and guess what? You can be Sparked too! I am authentically living in full awareness of my Sparketype® profile, which is made up of three elements that represent your strongest impulses and drivers.

Debbie Afasano

There are 10 Sparketypes®, identified through two decades of data analysis. Each of us has a blend of three Sparketype® elements that will be identified and further understood after taking your Sparketype® Assessment and participating in our first ever Sparketype® "Discover Your Unique Imprint" workshop for LTC at FADONA on March 20.

The 10 defined Sparketypes® are: Maven, Maker, Scientist, Essentialist, Performer, Sage, Warrior, Advisor, Advocate, and Nurturer. Remember, you are individually Sparketype® assessed and a blend of three of the Sparketypes®! Don't worry about the details behind them. We will have ample interactive time and opportunities to discover you own unique imprint.

In addition, you will get a free copy of the incredible "SPARKED" book by Jonathan Fields.

1. Your Primary Sparketype® is the underlying driver or "Source fuel" for work that makes you feel alive and living within your purpose. It is work that you are instinctively drawn to and fueled by.

2. Your Shadow is also a strong driving impulse within you, but not quite as powerful as the Primary. It is a type of amplifier for your Primary instincts and complements those instincts or drivers. It is like the first runner up in what sparks you! Your Primary and Shadow Sparketypes® are partners and collaborators.

3. Your Anti Spark is the part of work that is most draining, takes the most out of you, and is the heaviest lift. It does not mean that you are not competent in these areas. It just identifies what takes the most out of you and demands more recovery time. Understanding your own drivers allows you to identify how you show up in your work, and how you can realign, reinvent, or reimagine yourself!

For those of you that know me, you might describe me as empathetic, compassionate, and warmhearted. I am fueled by being of service to others and developing positive connections and relationships. It was no surprise to me that my primary Sparketype® is "The Nurturer." The tagline for the Nurturer is "I've Got You."

Experiencing excitement, positive energy, engagement, and enthusiasm as you pursue that purpose that is unique to you!

As a nurse that seems to be a natural fit. I am a caring magnet. I care about serving others, being hands on in service, and the center of any opportunity to nurture, uplift, and be a grounding presence. People seek me out in clinical settings, community gatherings, Facebook messaging and Publix! I care for people, pets, and common humanistic opportunities.

My shadow Sparketype® is the amplifier for my Nurturer impulse and works hard to benefit the passion of the Primary. My shadow is… wait for it… Ta-da and drum roll, "The Performer™! My tagline is, "I Turn Moments into Magic." The Performer may be described as stimulating, rousing, inspiring, and dynamic. My sister calls me a "Character" if that gives you any insight! The Performer likes engagement and interaction. My performer works right next to the Nurturer to pursue and connect people to life, an emotion, and an experience.

Early in life we may begin to show intrinsic impulses or affinities for certain types of work. I am living proof of this. When I was two years old my parents took me to an upscale restaurant called The Old Mill. I proceeded to stand on my chair and sing for the diners. The waitress came up to me and said, "I bet you will be a performer when you grow up." I then stopped my song and shouted at the top of my lungs, "I want to be a nurse!" Hum mm very interesting that my Primary is a Nurturer, and my Shadow is the Performer. I partner with both of them on a regular basis. If you really want to see them in action, attend the Annual Convention keynote on Tuesday, March 21, "IMA Walking Down Memory Lane!" They will definitely demonstrate the concept of being SPARKED.

For most people, determining your Sparketype® profile is like being introduced to your true self. Often there is an immediate "Aha," a knowing that occurs along with a sense of freedom that evolves from identifying "Yes this is me."

What it takes to be Sparked requires existing in what is often called the sweet spot of 5 Domains. When fully Sparked you are aligned and working in partnership with your Sparketypes®. When you are in that special place you can affirm that you are:

1. Living in your purpose and moving towards something you believe in.

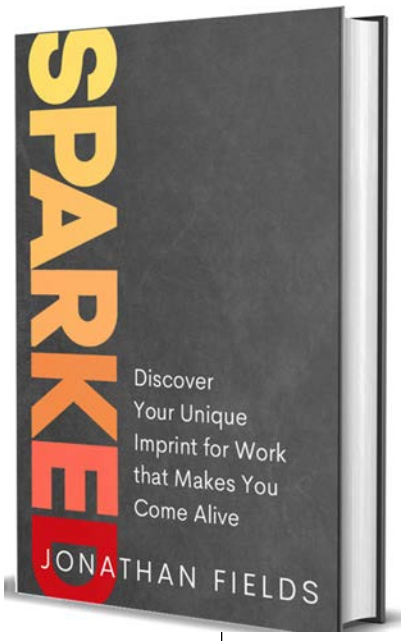
2. Experiencing excitement, positive energy, engagement, and enthusiasm as you pursue that purpose that is unique to you!

3. Experiencing what is referred to as "meaningfulness." When meaningfulness is happening you know from your head to your toes that you are doing something special and that who you are truly matters. Don't we all yearn for that?

4. Being fully and truly yourself without hiding parts of you and/or holding back. That awesome awareness when you are fully expressing your potential and leaving nothing untapped!

5. Living and being in the F-L-O-W! Living in a place where you are lost in a meaningful activity, immersed in purpose, and being your true self. Time slips away. You are absorbed in a meaningful task and life is good!

So if you want to be SPARKED, the first step is signing up for the FADONA preconvention workshop. It offers 6 CEUs and is titled, "Sparketype®; Discover Your Unique Imprint." Once you are signed up, take the FREE Sparketype™ Assessment developed by Jonathan Fields. Go to **www.sparketype.com**, take the free assessment, and then email me your Sparketype® results care of Debbie Afasano at **carpediemhcc@gmail.com**. Please make EVERY EFFORT to send this to me by March 16, 2023. The three elements I need are your Primary/Shadow and Anti spark. For instance I am a Primary Nurturer/Shadow Performer, and Anti Spark Essentialist.



It is so important to get the most out of your SPARKED workshop experience. Make the time to invest in yourself and send me your SPARKETYPE® profile so that I can be totally vested in your experience. After you take the assessment, which only takes about 10 minutes, (and is specific to how you respond to the questions); they will email you a response with your profile.

Here is a bit of history to connect the dots of why I hope you will join me in our Introduction to Sparketype® Workshop. Jonathan Fields has mentored me over the past year, after I was interviewed and selected to become part of his limited national certification program. My certification required extensive case study review, process applications, certification exam, and ongoing learning and mentoring events. Jonathan helped me identify and embrace my Sparketypes®. Together we identified an incredible opportunity to introduce this program to the post COVID health care community that was in need of validation, inspiration, reengagement, and redefined purpose.

For me, it felt like I was rising up to answer a call that was part of my own imprints. I used my working knowledge of my own unique imprints to pursue becoming a Certified Sparketype Advisor (CSA™). I am now on my own purposeful journey, to connect people to their unique Sparketype® imprint.

I am honored to be connected to Jonathan Fields and this program. He is a dad, husband, award-winning author, executive producer, and host of one of the top-ranked podcasts in the world, Good Life Project®, which has been featured everywhere from *The Wall Street Journal* to *Oprah Magazine* and even Apple's iconic annual product event. He is also the Founder/CEO of Spark Endeavors and lead architect behind the Sparketypes®, an archetyping system and set of tools tapped by over 775,000 individuals and organizations and creating over 39 million data points that identify, embrace, and cultivate work that makes people come alive, and equip organizations and leaders to more-effectively unlock potential, motivation, impact, and joy.

Won't you join me and get SPARKED? ◆

Experiencing what is referred to as "meaningfulness." When meaningfulness is happening you know from your head to your toes that you are doing something special and that who you are truly matters. Don't we all yearn for that?

Support the Patches Bryan Scholarship

With our Fun, Homemade, Themed Gift Basket Contest & Silent Auction

We invite all members, convention attendees, and exhibitors to donate themed, homemade gift baskets for the silent auction at the Annual Trade Show.

Baskets will be judged by a panel of Platinum Partners, and the top three will receive an Amazon e-gift card **($100, $50, or $25)** during Fun Night.

Judges will be looking for the

Most Creative, Most Number of Bids,* and *Highest Dollar Bid.

All proceeds will benefit the **Patches Bryan Scholarship**. Over the years, FADONA has provided more than **$42,500** in scholarships to its members and their staff, and with your support, we will be able to continue this noble tradition. For more information, please call **Shane Bellotti** at the FADONA business office, **(561) 689-6321**.

Thanks for Your Donated Baskets!

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for subcutaneous use

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Otrexup is indicated for the[1]:

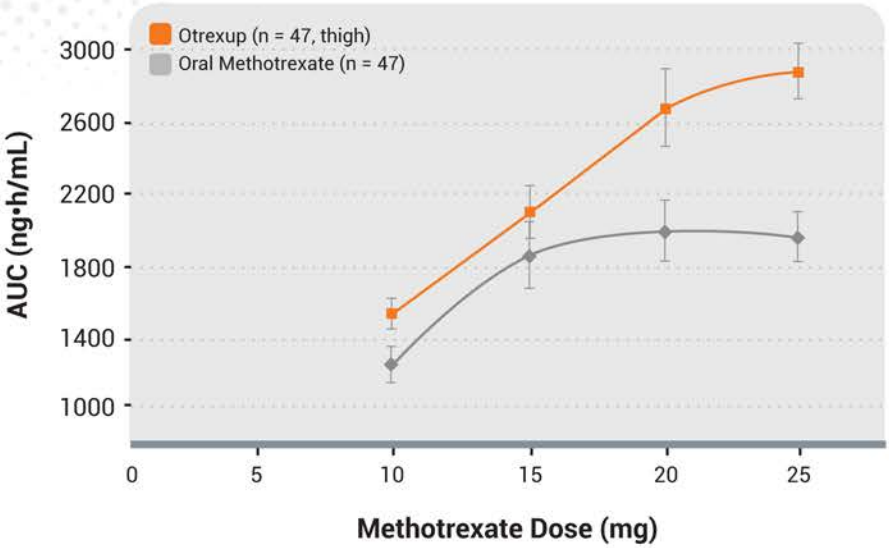
- Management of patients with severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA), who are intolerant of or had an inadequate response to first-line therapy
- Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy

LIMITATIONS OF USE:

OTREXUP is not indicated for the treatment of neoplastic diseases.

Bioavailability was higher with Otrexup when compared to oral methotrexate at the same dose

Relative Systemic Bioavailability of Otrexup vs Oral Methotrexate[2]



In adults, oral absorption appears to be dose dependent. Peak serum levels are reached within 1 to 2 hours. At doses of 30 mg/m^2 or less, methotrexate is generally well absorbed with a mean bioavailability of about 60%. The absorption of doses greater than 80 mg/m^2 is significantly less, possibly due to a saturation effect.[1]

In relative bioavailability studies in RA patients, systemic exposure of methotrexate was found to be similar between Otrexup and intramuscular or subcutaneous administration of methotrexate injection at the same doses; **however, systemic exposure of methotrexate was higher with Otrexup as compared to oral administration of methotrexate at the same dose.**[1]

Bioavailability following oral dosing showed a plateau effect at doses of 15 mg and greater. The systemic exposure of methotrexate from Otrexup at doses of 10, 15, 20, and 25 mg was higher than that of oral methotrexate by 17, 13, 31, and 36%, respectively. Methotrexate systemic absorption from Otrexup was similar when administered into the abdomen or thigh.[1]

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE TOXIC REACTIONS, INCLUDING EMBRYOFETAL TOXICITY AND DEATH

OTREXUP should be used only by physicians whose knowledge and experience include the use of antimetabolite therapy. Because of the possibility of serious toxic reactions (which can be fatal), OTREXUP should be used only in patients with psoriasis or rheumatoid arthritis with severe, recalcitrant, disabling disease which is not adequately responsive to other forms of therapy. Deaths have been reported with the use of methotrexate in the treatment of malignancy, psoriasis, and rheumatoid arthritis. Patients should be closely monitored for bone marrow, liver, lung, skin, and kidney toxicities. Patients should be informed by their physician of the risks involved and be under a physician's care throughout therapy.

1. **Methotrexate can cause embryofetal toxicity, including fetal death. Use is contraindicated during pregnancy. Verify the pregnancy status of females of reproductive potential prior to initiating therapy. Advise females and males of reproductive potential to use effective contraception during and after treatment with OTREXUP.**
2. **Methotrexate elimination is reduced in patients with impaired renal functions, ascites, or pleural effusions. Such patients require especially careful monitoring for toxicity, and require dose reduction or, in some cases, discontinuation of OTREXUP administration.**
3. **Unexpectedly severe (sometimes fatal) bone marrow suppression, aplastic anemia, and gastrointestinal toxicity have been reported with concomitant administration of methotrexate (usually in high dosage) along with some nonsteroidal anti-inflammatory drugs (NSAIDs).**
4. **Methotrexate causes hepatotoxicity, fibrosis and cirrhosis, but generally only after prolonged use. Acutely, liver enzyme elevations are frequently seen. These are usually transient and asymptomatic, and also do not appear predictive of subsequent hepatic disease. Liver biopsy after sustained use often shows histologic changes, and fibrosis and cirrhosis have been reported; these latter lesions may not be preceded by symptoms or abnormal liver function tests in the psoriasis population. For this reason, periodic liver biopsies are usually recommended for psoriatic patients who are under long-term treatment. Persistent abnormalities in liver function tests may precede appearance of fibrosis or cirrhosis in the rheumatoid arthritis population.**
5. **Methotrexate-induced lung disease, including acute or chronic interstitial pneumonitis, is a potentially dangerous lesion, which may occur acutely at any time during therapy and has been reported at low doses. It is not always fully reversible, and fatalities have been reported. Pulmonary symptoms (especially a dry, nonproductive cough) may require interruption of treatment and careful investigation.**
6. **Diarrhea and ulcerative stomatitis require interruption of therapy: otherwise, hemorrhagic enteritis and death from intestinal perforation may occur.**
7. **Malignant lymphomas, which may regress following withdrawal of methotrexate, may occur in patients receiving low-dose methotrexate and, thus, may not require cytotoxic treatment. Discontinue OTREXUP first and, if the lymphoma does not regress, appropriate treatment should be instituted.**
8. **Like other cytotoxic drugs, methotrexate may induce "tumor lysis syndrome" in patients with rapidly growing tumors.**
9. **Severe, occasionally fatal, skin reactions have been reported following single or multiple doses of methotrexate. Reactions have occurred within days of oral, intramuscular, intravenous, or intrathecal methotrexate administration. Recovery has been reported with discontinuation of therapy.**
10. **Potentially fatal opportunistic infections, especially *Pneumocystis jiroveci* pneumonia, may occur with methotrexate therapy.**
11. **Methotrexate given concomitantly with radiotherapy may increase the risk of soft tissue necrosis and osteonecrosis.**

Please see additional Important Safety Information on next pages and the Brief Summary of the full Prescribing Information.

OTREXUP® (methotrexate) injection, for subcutaneous use

INDICATIONS:

OTREXUP is indicated in:

- the management of selected adults with severe, active rheumatoid arthritis (RA) (ACR criteria), or children with active polyarticular juvenile idiopathic arthritis (pJIA), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).
- in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation. It is important to ensure that a psoriasis "flare" is not due to an undiagnosed concomitant disease affecting immune responses.

LIMITATIONS OF USE:

OTREXUP is not indicated for the treatment of neoplastic diseases.

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS:

OTREXUP is contraindicated in the following:

- **Pregnancy:** OTREXUP can cause embryo-fetal toxicity and fetal death when administered during pregnancy.
- **Alcoholism or Liver Disease:** Patients with alcoholism, alcoholic liver disease or other chronic liver disease.
- **Immunodeficiency Syndromes:** Patients who have overt or laboratory evidence of immunodeficiency syndromes.
- **Preexisting Blood Dyscrasias:** Patients who have preexisting blood dyscrasias, such as bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anemia.
- **Hypersensitivity:** Patients with a known hypersensitivity to methotrexate. Severe hypersensitivity reactions have been observed with methotrexate use.

WARNINGS AND PRECAUTIONS:

- **Organ System Toxicity:** OTREXUP should be used only by physicians whose knowledge and experience include the use of antimetabolite therapy. Because of the possibility of serious toxic reactions (which can be fatal), OTREXUP should be used only in patients with psoriasis or rheumatoid arthritis with severe, recalcitrant, disabling disease which is not adequately responsive to other forms of therapy.

  Deaths have been reported with the use of methotrexate in the treatment of malignancy, psoriasis, and rheumatoid arthritis. Patients should be closely monitored for bone marrow, liver, lung and kidney toxicities.

  Toxic effects may be related in frequency and severity to dose or frequency of administration but have been seen at all doses. Because they can occur at any time during therapy, it is necessary to follow patients on OTREXUP closely.
- *Gastrointestinal:* Diarrhea and ulcerative stomatitis require interruption of therapy: otherwise, hemorrhagic enteritis and death may occur. OTREXUP should be discontinued until recovery occurs. Use with extreme caution in the presence of peptic ulcer disease or ulcerative colitis. OTREXUP may cause unexpectedly severe (sometimes fatal) gastrointestinal toxicity when used with NSAIDs.
- *Hematologic:* OTREXUP can suppress hematopoiesis and cause anemia, aplastic anemia, pancytopenia, leukopenia, neutropenia, and/or thrombocytopenia. In patients with preexisting hematopoietic impairment, OTREXUP should be used with caution, if at all. OTREXUP should be stopped immediately if there is a significant drop in blood counts. Unexpectedly severe (sometimes fatal) bone marrow suppression and aplastic anemia have been reported with concomitant administration of methotrexate (usually in high dosage) with NSAIDs.
- *Hepatic:* OTREXUP has the potential for acute (elevated transaminases) and chronic (fibrosis and cirrhosis) hepatotoxicity. Chronic toxicity is potentially fatal. Liver function should be monitored.
- *Infection or Immunologic States:* OTREXUP should be used with extreme caution in the presence of active infection, and is contraindicated in patients with overt or laboratory evidence of immunodeficiency syndromes.
- *Neurologic:* There have been reports of leukoencephalopathy following intravenous administration of methotrexate to patients who have had craniospinal irradiation. Serious neurotoxicity, frequently manifested as generalized or focal seizures, has been reported with unexpectedly increased frequency among pediatric patients with acute lymphoblastic leukemia. Chronic leukoencephalopathy has also been reported in patients who received repeated high doses of methotrexate with leucovorin rescue even without cranial irradiation. A transient acute neurologic syndrome has been observed.
- *Pulmonary:* Methotrexate-induced lung disease, including acute or chronic interstitial pneumonitis, is a potentially dangerous lesion, which may occur acutely at any time during therapy and has been reported at low doses. It is not always fully reversible, and fatalities have been reported.
- *Renal:* OTREXUP may cause renal damage that may lead to acute renal failure.
- *Skin:* Severe, occasionally fatal, dermatologic reactions, including toxic epidermal necrolysis, Stevens-Johnson syndrome, exfoliative dermatitis, skin necrosis, and erythema multiforme, have been reported in children and adults, within days of oral, intramuscular, intravenous, or intrathecal methotrexate administration. Reactions were noted after single or multiple low, intermediate, or high doses of methotrexate in patients with neoplastic and non-neoplastic diseases.
- *Other Precautions:* OTREXUP should be used with extreme caution in the presence of debility.
- **Embryo-Fetal Toxicity:** Based on published reports and methotrexate's mechanism of action, methotrexate can cause embryo-fetal toxicity and fetal death when administered to a pregnant woman. In pregnant women OTREXUP is contraindicated. Verify pregnancy status in females of reproductive potential prior to initiating OTREXUP. Advise females of reproductive potential to use effective contraception during treatment with OTREXUP and for 6 months after the final dose. Advise males of reproductive potential to use effective contraception during OTREXUP treatment and for at least 3 months after the final dose.
- **Effects on Reproduction:** Based on published reports, methotrexate can cause impairment of fertility, oligospermia, and menstrual dysfunction. It is not known if the infertility is reversible in affected patients. Discuss the risk of effects on reproduction with female and male patients of reproductive potential.
- **Laboratory Tests:** Patients undergoing OTREXUP therapy should be closely monitored so that toxic effects are detected promptly. Baseline assessment should include a complete blood count with differential and platelet counts, hepatic enzymes, renal function tests and a chest X-ray. During therapy, monitoring of these parameters is recommended: hematology at least monthly, renal function and liver function every 1 to 2 months. Pulmonary function tests may be useful if methotrexate-induced lung disease is suspected.
- **Risks from Improper Dosing:** Both the physician and pharmacist should emphasize to the patient that OTREXUP is administered weekly and that mistaken daily use has led to fatal toxicity.
- **Patients with Impaired Renal Function, Ascites, or Pleural Effusions:** Methotrexate elimination is reduced in patients with impaired renal function, ascites, or pleural effusions. Such patients require especially careful monitoring for toxicity and require dose reduction or, in some cases, discontinuation of OTREXUP administration.
- **Dizziness and Fatigue:** Adverse reactions, such as dizziness and fatigue, may affect the ability to drive or operate machinery.
- **Malignant Lymphomas:** Non-Hodgkin's lymphoma and other tumors have been reported in patients receiving low-dose oral methotrexate. However, there have been instances of malignant lymphoma arising during treatment with low-dose oral methotrexate, which have regressed completely following withdrawal of methotrexate, without requiring active anti-lymphoma treatment. Discontinue OTREXUP first and, if the lymphoma does not regress, appropriate treatment should be instituted.
- **Tumor Lysis Syndrome:** Like other cytotoxic drugs, methotrexate may induce "tumor lysis syndrome" in patients with rapidly growing tumors.
- **Concomitant Radiation Therapy:** Methotrexate given concomitantly with radiotherapy may increase the risk of soft tissue necrosis and osteonecrosis.

Please see additional Important Safety Information on next pages and the Brief Summary of the full Prescribing Information.

ADVERSE REACTIONS:

Common adverse reactions are: nausea, abdominal pain/distress, dyspepsia, ulcerative stomatitis/mouth sores, rash, nasopharyngitis, diarrhea, liver function test abnormalities, vomiting, headache, bronchitis, thrombocytopenia, alopecia, leucopenia, pancytopenia, dizziness, photosensitivity, and "burning of skin lesions." Other frequently reported adverse reactions are malaise, undue fatigue, chills and fever, and decreased resistance to infection.

DRUG INTERACTIONS:

- **Aspirin, Nonsteroidal Anti-Inflammatory Drugs, and Steroids:** Nonsteroidal anti-inflammatory drugs (NSAIDs) should not be administered prior to or concomitantly with the high doses of methotrexate. Concomitant administration of some NSAIDs with high dose methotrexate therapy has been reported to elevate and prolong serum methotrexate levels, resulting in deaths from severe hematologic and gastrointestinal toxicity. Caution should be used when NSAIDs and salicylates are administered concomitantly with lower doses of methotrexate, including OTREXUP.
- **Proton Pump Inhibitors (PPIs):** The concomitant use of some PPIs, such as omeprazole, esomeprazole, and pantoprazole, with methotrexate (primarily at high dose), may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxymethotrexate, possibly leading to methotrexate toxicities.
- **Oral Antibiotics:** Oral antibiotics such as tetracycline, chloramphenicol, and nonabsorbable broad spectrum antibiotics, may decrease intestinal absorption of methotrexate or interfere with the enterohepatic circulation by inhibiting bowel flora and suppressing metabolism of the drug by bacteria. Penicillins may reduce the renal clearance of methotrexate, resulting in hematologic and gastrointestinal toxicity. Use of OTREXUP with penicillins should be carefully monitored. Trimethoprim/sulfamethoxazole has been reported rarely to increase bone marrow suppression in patients receiving methotrexate.
- **Hepatotoxins:** Patients receiving concomitant therapy with OTREXUP and other potential hepatotoxins (e.g., azathioprine, retinoids, and sulfasalazine) should be closely monitored for possible increased risk of hepatotoxicity.
- **Theophylline:** Methotrexate may decrease the clearance of theophylline; theophylline levels should be monitored when used concurrently with OTREXUP.
- **Folic Acid and Antifolates:** Vitamin preparations containing folic acid or its derivatives may decrease responses to systemically administered methotrexate. Folate deficiency states may increase methotrexate toxicity.
- **Mercaptopurine:** Methotrexate increases the plasma levels of mercaptopurine. The combination of OTREXUP and mercaptopurine may therefore require dose adjustment.
- **Nitrous Oxide:** The use of nitrous oxide anesthesia potentiates the effect of methotrexate on folate dependent metabolic pathways, resulting in the potential for increased toxicity. Avoid concomitant nitrous oxide anesthesia in patients receiving methotrexate.
- **Other Drugs:** Methotrexate is partially bound to serum albumin, and toxicity may be increased because of displacement by certain drugs such as salicylates, phenylbutazone, phenytoin, and sulfonamides. Renal tubular transport is also diminished by probenecid; use of OTREXUP with this drug should be carefully monitored.

USE IN SPECIAL POPULATIONS:

- **Pregnancy:** Methotrexate has been reported to cause embryo-fetal toxicity, fetal death, congenital anomalies, and abortion in humans and is contraindicated in pregnant women.
- **Nursing Mothers:** Methotrexate is present in human milk in low amounts following oral methotrexate administration. Because of the potential for serious adverse reactions including myelosuppression, from methotrexate in breastfed infants, advise women not to breastfeed during treatment with OTREXUP and for one week after the final dose.
- **Females and Males of Reproductive Potential:** Verify the pregnancy status of females of reproductive potential prior to initiating OTREXUP. Advise females of reproductive potential to use effective contraception during and for 6 months after the final dose of OTREXUP. Advise males with female partners of reproductive potential to use effective contraception during and for at least 3 months after the final dose of OTREXUP. OTREXUP can cause impairment of fertility and menstrual dysfunction during and after cessation of therapy. It is not known if the infertility may be reversed in all affected females. OTREXUP can cause oligospermia or infertility during and after cessation of therapy. It is not known if the infertility may be reversed in all affected males.
- **Pediatric Use:** The safety and effectiveness of methotrexate, including OTREXUP, have not been established in pediatric patients with psoriasis. The safety and effectiveness of OTREXUP have not been established in pediatric patients with neoplastic diseases. Serious neurotoxicity, frequently manifested as generalized or focal seizures, has been reported with unexpectedly increased frequency among pediatric patients with acute lymphoblastic leukemia treated with intermediate-dose intravenous methotrexate.
- **Geriatric Use:** Use caution in dose selection for elderly patients due to the greater frequency of decreased hepatic and renal function, decreased folate stores, concomitant disease, or other drug therapy in this population. Elderly patients should be closely monitored for early signs of hepatic, bone marrow and renal toxicity.
- **Renal Impairment:** Methotrexate elimination is reduced in patients with impaired renal function. Such patients require especially careful monitoring for toxicity and require dose reduction or, in some cases, discontinuation of OTREXUP administration.
- **Hepatic Impairment:** OTREXUP is contraindicated in patients with alcoholic liver disease or other chronic liver disease. Patients with obesity, diabetes, hepatic fibrosis or steatohepatitis are at increased risk for hepatic injury and fibrosis secondary to methotrexate, and should be monitored closely.

DOSAGE AND ADMINISTRATION:

OTREXUP is for once weekly subcutaneous use only. Administer OTREXUP in the abdomen or thigh.

Please see Brief Summary of full Prescribing Information on next page.

To report SUSPECTED ADVERSE REACTIONS, contact Assertio Therapeutics at 1-800-518-1084 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References
1. Otrexup Prescribing Information. Antares Pharma Inc; 2019.
2. Schiff MH, Jaffe JS, Freundlich B. Head-to-head, randomised, crossover study of oral versus subcutaneous methotrexate in patients with rheumatoid arthritis: drug-exposure limitations of oral methotrexate at doses ≥15 mg may be overcome with subcutaneous administration. *Ann Rheum Dis*. 2014;73(8):1549-1551.

Please see the Brief Summary of the full Prescribing Information on the following pages.

Brief Summary of Prescribing Information for OTREXUP (methotrexate) injection, for subcutaneous use
Prescription Only. Initial U.S. Approval: 1953
Full Prescribing Information is available at https://otrexup.com/pi or by calling 1-800-518-1084

WARNING: SEVERE TOXIC REACTIONS, INCLUDING EMBRYO-FETAL TOXICITY AND DEATH

Otrexup should be used only by physicians whose knowledge and experience include the use of antimetabolite therapy. Because of the possibility of serious toxic reactions (which can be fatal), Otrexup should be used only in patients with psoriasis or rheumatoid arthritis with severe, recalcitrant, disabling disease which is not adequately responsive to other forms of therapy. Deaths have been reported with the use of methotrexate in the treatment of malignancy, psoriasis, and rheumatoid arthritis. Patients should be closely monitored for bone marrow, liver, lung, skin, and kidney toxicities. Patients should be informed by their physician of the risks involved and be under a physician's care throughout therapy.

1. Methotrexate can cause embryo-fetal toxicity, including fetal death. Use is contraindicated during pregnancy. Verify the pregnancy status of females of reproductive potential prior to initiating therapy. Advise females and males of reproductive potential to use effective contraception during and after treatment with Otrexup.

2. Methotrexate elimination is reduced in patients with impaired renal functions, ascites, or pleural effusions. Such patients require especially careful monitoring for toxicity, and require dose reduction or, in some cases, discontinuation of Otrexup administration.

3. Unexpectedly severe (sometimes fatal) bone marrow suppression, aplastic anemia, and gastrointestinal toxicity have been reported with concomitant administration of methotrexate (usually in high dosage) along with some nonsteroidal anti-inflammatory drugs (NSAIDs).

4. Methotrexate causes hepatotoxicity, fibrosis and cirrhosis, but generally only after prolonged use. Acutely, liver enzyme elevations are frequently seen. These are usually transient and asymptomatic, and also do not appear predictive of subsequent hepatic disease. Liver biopsy after sustained use often shows histologic changes, and fibrosis and cirrhosis have been reported; these latter lesions may not be preceded by symptoms or abnormal liver function tests in the psoriasis population. For this reason, periodic liver biopsies are usually recommended for psoriatic patients who are under long-term treatment. Persistent abnormalities in liver function tests may precede appearance of fibrosis or cirrhosis in the rheumatoid arthritis population.

5. Methotrexate-induced lung disease, including acute or chronic interstitial pneumonitis, is a potentially dangerous lesion, which may occur acutely at any time during therapy and has been reported at low doses. It is not always fully reversible and fatalities have been reported. Pulmonary symptoms (especially a dry, nonproductive cough) may require interruption of treatment and careful investigation.

6. Diarrhea and ulcerative stomatitis require interruption of therapy: otherwise, hemorrhagic enteritis and death from intestinal perforation may occur.

7. Malignant lymphomas, which may regress following withdrawal of methotrexate, may occur in patients receiving low-dose methotrexate and, thus, may not require cytotoxic treatment. Discontinue Otrexup first and, if the lymphoma does not regress, appropriate treatment should be instituted.

8. Like other cytotoxic drugs, methotrexate may induce "tumor lysis syndrome" in patients with rapidly growing tumors.

9. Severe, occasionally fatal, skin reactions have been reported following single or multiple doses of methotrexate. Reactions have occurred within days of oral, intramuscular, intravenous, or intrathecal methotrexate administration. Recovery has been reported with discontinuation of therapy.

10. Potentially fatal opportunistic infections, especially *Pneumocystis jiroveci* pneumonia, may occur with methotrexate therapy.

11. Methotrexate given concomitantly with radiotherapy may increase the risk of soft tissue necrosis and osteonecrosis.

CONTRAINDICATIONS

Otrexup is contraindicated in the following: • Pregnancy Otrexup can cause embryo-fetal toxicity and fetal death when administered during pregnancy. • Alcoholism or Liver Disease Patients with alcoholism, alcoholic liver disease or other chronic liver disease. • Immunodeficiency Syndromes Patients who have overt or laboratory evidence of immunodeficiency syndromes. • Preexisting Blood Dyscrasias Patients who have preexisting blood dyscrasias, such as bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anemia. • Hypersensitivity Patients with a known hypersensitivity to methotrexate. Severe hypersensitivity reactions have been observed with methotrexate use.

WARNINGS AND PRECAUTIONS

Organ System Toxicity. Otrexup should be used only by physicians whose knowledge and experience include the use of antimetabolite therapy. Because of the possibility of serious toxic reactions (which can be fatal), Otrexup should be used only in patients with psoriasis or rheumatoid arthritis with severe, recalcitrant, disabling disease which is not adequately responsive to other forms of therapy.

Deaths have been reported with the use of methotrexate in the treatment of malignancy, psoriasis, and rheumatoid arthritis. Patients should be closely monitored for bone marrow, liver, lung and kidney toxicities.

Otrexup has the potential for serious toxicity. Toxic effects may be related in frequency and severity to dose or frequency of administration but have been seen at all doses. Because they can occur at any time during therapy, it is necessary to follow patients on Otrexup closely. Most adverse reactions are reversible if detected early. When such reactions do occur, the drug should be reduced in dosage or discontinued and appropriate corrective measures should be taken. If necessary, this could include the use of leucovorin calcium and/or acute, intermittent hemodialysis with a high-flux dialyzer. If Otrexup therapy is reinstituted, it should be carried out with caution, with adequate consideration of further need for the drug and increased alertness as to possible recurrence of toxicity.

The clinical pharmacology of methotrexate has not been well studied in older individuals. Due to diminished hepatic and renal function as well as decreased folate stores in this population, relatively low doses should be considered, and these patients should be closely monitored for early signs of toxicity.

Gastrointestinal: Diarrhea and ulcerative stomatitis require interruption of therapy: otherwise, hemorrhagic enteritis and death from intestinal perforation may occur. If vomiting, diarrhea, or stomatitis occur, which may result in dehydration, Otrexup should be discontinued until recovery occurs. Otrexup should be used with extreme caution in the presence of peptic ulcer disease or ulcerative colitis. Unexpectedly severe (sometimes fatal) gastrointestinal toxicity has been reported with concomitant administration of methotrexate (usually in high dosage) along with some nonsteroidal anti-inflammatory drugs (NSAIDs).
Hematologic: Otrexup can suppress hematopoiesis and cause anemia, aplastic anemia, pancytopenia, leukopenia, neutropenia, and/or thrombocytopenia. In patients with preexisting hematopoietic impairment, Otrexup should be used with caution, if at all. In controlled clinical trials conducted with another formulation of methotrexate in rheumatoid arthritis (n=128), leukopenia (WBC <3000/mm^3) was seen in 2 patients, thrombocytopenia (platelets <100,000/mm^3) in 6 patients, and pancytopenia in 2 patients. Otrexup should be stopped immediately if there is a significant drop in blood counts. Patients with profound granulocytopenia and fever should be evaluated immediately and usually require parenteral broad-spectrum antibiotic therapy. Unexpectedly severe (sometimes fatal) bone marrow suppression and aplastic anemia have been reported with concomitant administration of methotrexate (usually in high dosage) along with some nonsteroidal anti-inflammatory drugs (NSAIDs).
Hepatic: Otrexup has the potential for acute (elevated transaminases) and chronic (fibrosis and cirrhosis) hepatotoxicity. Chronic toxicity is potentially fatal; it generally has occurred after prolonged use (generally two years or more) and after a total dose of at least 1.5 grams. In studies in psoriatic patients, hepatotoxicity appeared to be a function of total cumulative dose and appeared to be enhanced by alcoholism, obesity, diabetes and advanced age. An accurate incidence rate has not been determined; the rate of progression and reversibility of lesions is not known. Special caution is indicated in the presence of preexisting liver damage or impaired hepatic function.

In psoriasis, liver function tests, including serum albumin, should be performed periodically prior to dosing but are often normal in the face of developing fibrosis or cirrhosis. These lesions may be detectable only by biopsy. The usual recommendation is to obtain a liver biopsy at 1) pretherapy or shortly after initiation of therapy (2 to 4 months), 2) a total cumulative dose of 1.5 grams, and 3) after each additional 1.0 to 1.5 grams. Moderate fibrosis or any cirrhosis normally leads to discontinuation of the drug; mild fibrosis normally suggests a repeat biopsy in 6 months.

Milder histologic findings such as fatty change and low grade portal inflammation, are relatively common pretherapy. Although these mild changes are usually not a reason to avoid or discontinue Otrexup therapy, the drug should be used with caution.

In rheumatoid arthritis, age at first use of methotrexate and duration of therapy have been reported as risk factors for hepatotoxicity; other risk factors, similar to those observed in psoriasis, may be present in rheumatoid arthritis but have not been confirmed to date. Persistent abnormalities in liver function tests may precede appearance of fibrosis or cirrhosis in this population. There is a combined reported experience in 217 rheumatoid arthritis patients with liver biopsies both before and during treatment (after a cumulative dose of at least 1.5 g) and in 714 patients with a biopsy only during treatment. There are 64 (7%) cases of fibrosis and 1 (0.1%) case of cirrhosis. Of the 64 cases of fibrosis, 60 were deemed mild. The reticulin stain is more sensitive for early fibrosis and its use may increase these figures. It is unknown whether even longer use will increase these risks.

Liver function tests should be performed at baseline at 4 to 8 week intervals in patients receiving Otrexup for rheumatoid arthritis. Pretreatment liver biopsy should be performed for patients with a history of excessive alcohol consumption, persistently abnormal baseline liver function test values or chronic hepatitis B or C infection. During therapy, liver biopsy should be performed if there are persistent liver function test abnormalities or there is a decrease in serum albumin below the normal range (in the setting of well controlled rheumatoid arthritis).

If the results of a liver biopsy show mild changes (Roenigk, grades I, II, IIIa), Otrexup may be continued and the patient monitored as per recommendations listed above. Otrexup should be discontinued in any patient who displays persistently abnormal liver function tests and refuses liver biopsy or in any patient whose liver biopsy shows moderate to severe changes (Roenigk grade IIIb or IV).

Infection or Immunologic States: Otrexup should be used with extreme caution in the presence of active infection, and is contraindicated in patients with overt or laboratory evidence of immunodeficiency syndromes. Immunization may be ineffective when given during Otrexup therapy. Immunization with live virus vaccines is generally not recommended. There have been reports of disseminated vaccinia infections after smallpox immunizations in patients receiving methotrexate therapy. Hypogammaglobulinemia has been reported rarely. Potentially fatal opportunistic infections, especially *Pneumocystis jiroveci* pneumonia, may occur with Otrexup therapy. When a patient presents with pulmonary symptoms, the possibility of *Pneumocystis jiroveci* pneumonia should be considered.
Neurologic: There have been reports of leukoencephalopathy following intravenous administration of methotrexate to patients who have had craniospinal irradiation. Serious neurotoxicity, frequently manifested as generalized or focal seizures, has been reported with unexpectedly increased frequency among pediatric patients with acute lymphoblastic leukemia who were treated with intermediate-dose intravenous methotrexate (1 gm/m^2). Symptomatic patients were commonly noted to have leukoencephalopathy and/or microangiopathic calcifications on diagnostic imaging studies. Chronic leukoencephalopathy has also been reported in patients who received repeated doses of high-dose methotrexate with leucovorin rescue even without cranial irradiation.

Discontinuation of methotrexate does not always result in complete recovery. A transient acute neurologic syndrome has been observed in patients treated with high dose regimens. Manifestations of this stroke-like encephalopathy may include confusion, hemiparesis, transient blindness, seizures and coma. The exact cause is unknown. After the intrathecal use of methotrexate, the central nervous system toxicity which may occur can be classified as follows: acute chemical arachnoiditis manifested by such symptoms as headache, back pain, nuchal rigidity, and fever; subacute myelopathy characterized by paraparesis/paraplegia associated with involvement with one or more spinal nerve roots; chronic leukoencephalopathy manifested by confusion, irritability, somnolence, ataxia, dementia, seizures and coma. This condition can be progressive and even fatal.
Pulmonary: Methotrexate-induced lung disease, including acute or chronic interstitial pneumonitis, is a potentially dangerous lesion, which may occur acutely at any time during therapy and has been reported at low doses. It is not always fully reversible and fatalities have been reported. Pulmonary symptoms (especially a dry nonproductive cough) or a non-specific pneumonitis occurring during Otrexup therapy may be indicative of a potentially dangerous lesion and require interruption of treatment and careful investigation. Although clinically variable, the typical patient with methotrexate induced lung disease presents with fever, cough, dyspnea, hypoxemia, and an infiltrate on chest X-ray; infection (including pneumonia) needs to be excluded. This lesion can occur at all dosages.
Renal: Otrexup may cause renal damage that may lead to acute renal failure. High doses of methotrexate used in the treatment of osteosarcoma may cause renal damage leading to acute renal failure. Nephrotoxicity is due primarily to the precipitation of methotrexate and 7-hydroxymethotrexate in the renal tubules. Close attention to renal function including adequate hydration, urine alkalinization and measurement of serum methotrexate and creatinine levels are essential for safe administration.
Skin: Severe, occasionally fatal, dermatologic reactions, including toxic epidermal necrolysis, Stevens-Johnson syndrome, exfoliative dermatitis, skin necrosis, and erythema multiforme, have been reported in children and adults, within days of oral, intramuscular, intravenous, or intrathecal methotrexate administration. Reactions were noted after single or multiple low, intermediate, or high doses of methotrexate in patients with neoplastic and non-neoplastic diseases. Lesions of psoriasis may be aggravated by concomitant exposure to ultraviolet radiation. Radiation dermatitis and sunburn may be “recalled” by the use of methotrexate.
Other precautions: Otrexup should be used with extreme caution in the presence of debility. Methotrexate exits slowly from third space compartments (e.g., pleural effusions or ascites). This results in a prolonged terminal plasma half-life and unexpected toxicity. In patients with significant third space accumulations, it is advisable to evacuate the fluid before treatment and to monitor plasma methotrexate levels.

Embryo-Fetal Toxicity. Based on published reports and methotrexate’s mechanism of action, methotrexate can cause embryo-fetal toxicity and fetal death when administered to a pregnant woman. In pregnant women Otrexup is contraindicated. Verify pregnancy status in females of reproductive potential prior to initiating Otrexup. Advise females of reproductive potential to use effective contraception during treatment with Otrexup and for 6 months after the final dose. Advise males of reproductive potential to use effective contraception during Otrexup treatment and for at least 3 months after the final dose.

Effects on Reproduction. Based on published reports, methotrexate can cause impairment of fertility, oligospermia, and menstrual dysfunction. It is not known if the infertility is reversible in affected patients. Discuss the risk of effects on reproduction with female and male patients of reproductive potential.

Laboratory Tests. Patients undergoing Otrexup therapy should be closely monitored so that toxic effects are detected promptly. Baseline assessment should include a complete blood count with differential and platelet counts, hepatic enzymes, renal function tests and a chest X-ray. During therapy, monitoring of these parameters is recommended: hematology at least monthly, renal function and liver function every 1 to 2 months. *During initial or changing doses*, or during periods of increased risk of elevated methotrexate blood levels (e.g., dehydration), more frequent monitoring may also be indicated.
Liver Function Tests: Transient liver function test abnormalities are observed frequently after methotrexate administration and are usually not cause for modification of methotrexate therapy. Persistent liver function test abnormalities, and/or depression of serum albumin may be indicators of serious liver toxicity and require evaluation. A relationship between abnormal liver function tests and fibrosis or cirrhosis of the liver has not been established for patients with psoriasis. Persistent abnormalities in liver function tests may precede appearance of fibrosis or cirrhosis in the rheumatoid arthritis population.
Pulmonary Function Tests: Pulmonary function tests may be useful if methotrexate-induced lung disease is suspected, especially if baseline measurements are available.

Risks from Improper Dosing. Both the physician and pharmacist should emphasize to the patient that Otrexup is administered weekly and that mistaken daily use has led to fatal toxicity.

Patients with Impaired Renal Function, Ascites, or Pleural Effusions. Methotrexate elimination is reduced in patients with impaired renal

function, ascites, or pleural effusions. Such patients require especially careful monitoring for toxicity and require dose reduction or, in some cases, discontinuation of Otrexup administration.

Dizziness and Fatigue. Adverse reactions, such as dizziness and fatigue, may affect the ability to drive or operate machinery.

Malignant Lymphomas. Non-Hodgkin's lymphoma and other tumors have been reported in patients receiving low-dose oral methotrexate. However, there have been instances of malignant lymphoma arising during treatment with low-dose oral methotrexate, which have regressed completely following withdrawal of methotrexate, without requiring active antilymphoma treatment. Discontinue Otrexup first and, if the lymphoma does not regress, appropriate treatment should be instituted.

Tumor Lysis Syndrome. Like other cytotoxic drugs, methotrexate may induce "tumor lysis syndrome" in patients with rapidly growing tumors.

Concomitant Radiation Therapy. Methotrexate given concomitantly with radiotherapy may increase the risk of soft tissue necrosis and osteonecrosis.

ADVERSE REACTIONS

The following adverse reactions are discussed in more detail in other sections of the labeling.

- Organ System Toxicity
- Embryo-Fetal Toxicity
- Effects on Reproduction
- Malignant Lymphomas

The most frequently reported adverse reactions include ulcerative stomatitis, leukopenia, nausea, and abdominal distress. Other frequently reported adverse reactions are malaise, undue fatigue, chills and fever, dizziness and decreased resistance to infection.

Clinical Trials Experience

This section provides a summary of adverse reactions reported in subjects in clinical studies conducted with Otrexup as well as with methotrexate injection and oral methotrexate. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates observed in practice.

Rheumatoid Arthritis: The approximate incidences of methotrexate-attributed (i.e. placebo rate subtracted) adverse reactions in 12 to 18 week double-blind studies of patients (n=128) with rheumatoid arthritis treated with low-dose oral (7.5 to 15 mg/week) pulse methotrexate, are listed below. Virtually all of these patients were on concomitant nonsteroidal anti-inflammatory drugs and some were also taking low dosages of corticosteroids. Hepatic histology was not examined in these short-term studies. Incidence greater than 10%: Elevated liver function tests 15%, nausea/vomiting 10%. Incidence 3% to 10%: Stomatitis, thrombocytopenia (platelet count less than 100,000/mm^3). Incidence 1% to 3%: Rash/pruritis/dermatitis, diarrhea, alopecia, leukopenia (WBC less than 3000/mm^3), pancytopenia, dizziness. Two other controlled trials of patients (n=680) with Rheumatoid Arthritis on 7.5 mg to 15 mg/wk oral doses showed an incidence of interstitial pneumonitis of 1%. Other less common reactions included decreased hematocrit, headache, upper respiratory infection, anorexia, arthralgias, chest pain, coughing, dysuria, eye discomfort, epistaxis, fever, infection, sweating, tinnitus, and vaginal discharge.

Polyarticular Juvenile Idiopathic Arthritis: The approximate incidences of adverse reactions reported in pediatric patients with pJIA treated with oral, weekly doses of methotrexate (5 to 20 mg/m^2/wk or 0.1 to 0.65 mg/kg/wk) were as follows (virtually all patients were receiving concomitant nonsteroidal anti-inflammatory drugs, and some also were taking low doses of corticosteroids): elevated liver function tests, 14%; gastrointestinal reactions (e.g., nausea, vomiting, diarrhea), 11%; stomatitis, 2%; leukopenia, 2%; headache, 1.2%; alopecia, 0.5%; dizziness, 0.2%; and rash, 0.2%. Although there is experience with dosing up to 30 mg/m^2/wk in pJIA, the published data for doses above 20 mg/m^2/wk are too limited to provide reliable estimates of adverse reaction rates.

Psoriasis: There are two literature reports (Roenigk, 1969, and Nyfors, 1978) describing large series (n=204, 248) of psoriasis patients treated with methotrexate. Dosages ranged up to 25 mg per week and treatment was administered for up to four years. With the exception of alopecia, photosensitivity, and "burning of skin lesions" (each 3% to 10%), the adverse reaction rates in these reports were very similar to those in the rheumatoid arthritis studies. Rarely, painful plaque erosions may appear (Pearce, HP and Wilson, BB: *Am Acad Dermatol* 35:835-838, 1996).

Other Adverse Reactions

Other adverse reactions that have been reported with methotrexate in oncology, RA, pJIA, and psoriasis patients are listed below by organ system.

Alimentary System: gingivitis, pharyngitis, stomatitis, anorexia, nausea, vomiting, diarrhea, hematemesis, melena, gastrointestinal ulceration and bleeding, enteritis, pancreatitis. ***Blood and Lymphatic System Disorders:*** suppressed hematopoiesis, anemia, aplastic anemia, pancytopenia, leukopenia, neutropenia, thrombocytopenia, agranulocytosis, eosinophilia, lymphadenopathy and lymphoproliferative disorders (including reversible). Hypogammaglobulinemia has been reported rarely. ***Cardiovascular:*** pericarditis, pericardial effusion, hypotension, and thromboembolic events (including arterial thrombosis, cerebral thrombosis, deep vein thrombosis, retinal vein thrombosis, thrombophlebitis, and pulmonary embolus). ***Central Nervous System:*** headaches, drowsiness, blurred vision, transient blindness, speech impairment including dysarthria and aphasia, hemiparesis, paresis and convulsions have also occurred following administration of methotrexate. Following low doses, there have been occasional reports of transient subtle cognitive dysfunction, mood alteration or unusual cranial sensations, leukoencephalopathy, or encephalopathy. ***Hepatobiliary Disorders:*** hepatotoxicity, acute hepatitis, chronic fibrosis and cirrhosis, hepatic failure, decrease in serum albumin, liver enzyme elevations. ***Infection:*** There have been case reports of sometimes fatal opportunistic infections in patients receiving methotrexate therapy for neoplastic and non-neoplastic diseases. *Pneumocystis jiroveci* pneumonia was the most common opportunistic infection. There have also been reports of infections, pneumonia, Cytomegalovirus infection, including cytomegaloviral pneumonia, sepsis, fatal sepsis, nocardiosis; histoplasmosis, cryptococcosis, *Herpes zoster*, *Herpes simplex* hepatitis, and disseminated *Herpes simplex*. ***Musculoskeletal System:*** stress fracture. ***Ophthalmic:*** conjunctivitis, serious visual changes of unknown etiology. ***Pulmonary System:*** respiratory fibrosis, respiratory failure, alveolitis, interstitial pneumonitis deaths have been reported, and chronic interstitial obstructive pulmonary disease has occasionally occurred. ***Skin:*** erythematous rashes, pruritus, urticaria, photosensitivity, pigmentary changes, alopecia, ecchymosis, telangiectasia, acne, furunculosis, erythema multiforme, toxic epidermal necrolysis, Stevens-Johnson syndrome, skin necrosis, skin ulceration and exfoliative dermatitis. ***Urogenital System:*** severe nephropathy or renal failure, azotemia, cystitis, hematuria, proteinuria; defective oogenesis or spermatogenesis, transient oligospermia, menstrual dysfunction, vaginal discharge, and gynecomastia; infertility, abortion, fetal death, fetal defects. Other rarer reactions related to or attributed to the use of methotrexate such as nodulosis, vasculitis, arthralgia/myalgia, loss of libido/ impotence, diabetes, osteoporosis, sudden death, lymphoma, including reversible lymphomas, tumor lysis syndrome, soft tissue necrosis and osteonecrosis. Anaphylactoid reactions have been reported.

DRUG INTERACTIONS

Aspirin, Nonsteroidal Anti-Inflammatory Drugs, and Steroids. Nonsteroidal anti-inflammatory drugs (NSAIDs) should not be administered prior to or concomitantly with the high doses of methotrexate, such as used in the treatment of osteosarcoma. Concomitant administration of some NSAIDs with high dose methotrexate therapy has been reported to elevate and prolong serum methotrexate levels, resulting in deaths from severe hematologic and gastrointestinal toxicity. Caution should be used when NSAIDs and salicylates are administered concomitantly with lower doses of methotrexate, including Otrexup. These drugs have been reported to reduce the tubular secretion of methotrexate in an animal model and may enhance its toxicity. Despite the potential interactions, studies of methotrexate in patients with rheumatoid arthritis have usually included concurrent use of constant dosage regimens of NSAIDs, without apparent problems. It should be appreciated, however, that the doses used in rheumatoid arthritis (7.5 to 15 mg/week) are somewhat lower than those used in psoriasis and that larger doses could lead to unexpected toxicity. Aspirin, NSAIDs, and/or low dose steroids may be continued, although the possibility of increased toxicity with concomitant use of NSAIDs including salicylates has not

been fully explored. Steroids may be reduced gradually in patients who respond to methotrexate.

Proton Pump Inhibitors (PPIs). Use caution if high-dose methotrexate is administered to patients receiving proton pump inhibitor (PPI) therapy. Case reports and published population pharmacokinetic studies suggest that concomitant use of some PPIs, such as omeprazole, esomeprazole, and pantoprazole, with methotrexate (primarily at high dose), may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxymethotrexate, possibly leading to methotrexate toxicities. In two of these cases, delayed methotrexate elimination was observed when high-dose methotrexate was coadministered with PPIs, but was not observed when methotrexate was co-administered with ranitidine. However, no formal drug interaction studies of methotrexate with ranitidine have been conducted.

Oral Antibiotics. Oral antibiotics such as tetracycline, chloramphenicol, and nonabsorbable broad spectrum antibiotics, may decrease intestinal absorption of methotrexate or interfere with the enterohepatic circulation by inhibiting bowel flora and suppressing metabolism of the drug by bacteria. Penicillins may reduce the renal clearance of methotrexate; increased serum concentrations of methotrexate with concomitant hematologic and gastrointestinal toxicity have been observed with high and low dose methotrexate. Use of Otrexup with penicillins should be carefully monitored. Trimethoprim/sulfamethoxazole has been reported rarely to increase bone marrow suppression in patients receiving methotrexate, probably by decreased tubular secretion and/or an additive antifolate effect.

Hepatotoxins. The potential for increased hepatotoxicity when methotrexate is administered with other hepatotoxic agents has not been evaluated. However, hepatotoxicity has been reported in such cases. Therefore, patients receiving concomitant therapy with Otrexup and other potential hepatotoxins (e.g., azathioprine, retinoids, and sulfasalazine) should be closely monitored for possible increased risk of hepatotoxicity.

Theophylline. Methotrexate may decrease the clearance of theophylline; theophylline levels should be monitored when used concurrently with Otrexup.

Folic Acid and Antifolates. Vitamin preparations containing folic acid or its derivatives may decrease responses to systemically administered methotrexate. Preliminary animal and human studies have shown that small quantities of intravenously administered leucovorin enter the CSF primarily as 5-methyltetrahydrofolate and, in humans, remain 1 to 3 orders of magnitude lower than the usual methotrexate concentrations following intrathecal administration. However, high doses of leucovorin may reduce the efficacy of intrathecally administered methotrexate. Folate deficiency states may increase methotrexate toxicity. Trimethoprim/sulfamethoxazole has been reported rarely to increase bone marrow suppression in patients receiving methotrexate, probably by decreased tubular secretion and/or an additive antifolate effect.

Mercaptopurine. Methotrexate increases the plasma levels of mercaptopurine. The combination of Otrexup and mercaptopurine may therefore require dose adjustment.

Nitrous Oxide. The use of nitrous oxide anesthesia potentiates the effect of methotrexate on folate dependent metabolic pathways, resulting in the potential for increased toxicity. Avoid concomitant nitrous oxide anesthesia in patients receiving methotrexate.

Other Drugs. Methotrexate is partially bound to serum albumin, and toxicity may be increased because of displacement by certain drugs, such as salicylates, phenylbutazone, phenytoin, and sulfonamides. Renal tubular transport is also diminished by probenecid; use of Otrexup with this drug should be carefully monitored. Combined use of methotrexate with gold, penicillamine, hydroxychloroquine, sulfasalazine, or cytotoxic agents, has not been studied and may increase the incidence of adverse effects.

USE IN SPECIFIC POPULATIONS

Pregnancy. *Risk Summary:* Based on published reports and methotrexate's mechanism of action, methotrexate can cause embryo-fetal toxicity and fetal death when administered to a pregnant woman. In pregnant women with non-malignant disease, Otrexup is contraindicated. Consider the benefits and risks of Otrexup and risks to the fetus when prescribing Otrexup to a pregnant patient. There are no animal data that meet current standards for nonclinical developmental toxicity studies. The estimated background risk of major birth defects and miscarriage for the indicated populations are unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Human Data: Published data from cases, literature reviews, and observational studies report that methotrexate exposure during pregnancy is associated with an increased risk of embryo-fetal toxicity and fetal death. Methotrexate exposure during the first trimester of pregnancy is associated with an increased incidence of spontaneous abortions and multiple adverse developmental outcomes, including skull anomalies, facial dysmorphism, central nervous system abnormalities, limb abnormalities, and sometimes cardiac anomalies and intellectual impairment. Adverse outcomes associated with exposure during second and third trimesters of pregnancy include intrauterine growth restriction and functional abnormalities. Because methotrexate is widely distributed and persists in the body for a prolonged period, there is a potential risk to the fetus from preconception methotrexate exposure. A prospective multicenter study evaluated pregnancy outcomes in women taking methotrexate less than or equal to 30 mg/week after conception. The rate of miscarriage in pregnant women exposed to methotrexate was 42.5% (95% confidence interval [95% CI] 29.2-58.7), which was higher than in unexposed patients with autoimmune disease (22.5%, 95% CI 16.8-29.7) and unexposed patients with non-autoimmune disease (17.3%, 95% CI 13-22.8). Of the live births, the rate of major birth defects in pregnant women exposed to methotrexate after conception was higher than in unexposed patients with autoimmune disease (adjusted odds ratio (OR) 1.8 [95% CI 0.6-5.7]) and unexposed patients with non-autoimmune disease (adjusted OR 3.1 [95% CI 1.03-9.5]). Major birth defects associated with pregnancies exposed to methotrexate after conception were not always consistent with methotrexate-associated adverse developmental outcomes.

Lactation. *Risk Summary:* Limited published literature report the presence of methotrexate in human milk in low amounts following oral methotrexate administration, with the highest breast milk to plasma concentration ratio reported to be 0.08:1. No information is available on the effects of methotrexate on a breastfed infant or on milk production. Because of the potential for serious adverse reactions including myelosuppression, from methotrexate in breastfed infants, advise women not to breastfeed during treatment with Otrexup and for one week after the final dose.

Females and Males of Reproductive Potential. *Pregnancy Testing:* Verify the pregnancy status of females of reproductive potential prior to initiating Otrexup.

Contraception: Females Otrexup can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during and for 6 months after the final dose of Otrexup. Males Methotrexate can cause chromosomal damage to sperm cells. Advise males with female partners of reproductive potential to use effective contraception during and for at least 3 months after the final dose of Otrexup.

Infertility: Females Based on published reports of female infertility after treatment with methotrexate, advise females of reproductive potential that Otrexup can cause impairment of fertility and menstrual dysfunction during and after cessation of therapy. It is not known if the infertility may be reversed in all affected females. Males Based on published reports of male infertility after treatment with methotrexate, advise males of reproductive potential that Otrexup can cause oligospermia or infertility during and after cessation of therapy. It is not known if the infertility may be reversed in all affected males.

Pediatric Use. The safety and effectiveness of methotrexate, including Otrexup, have not been established in pediatric patients with psoriasis. The safety and effectiveness of Otrexup have not been established in pediatric patients with neoplastic diseases. The safety and effectiveness of methotrexate have been established in pediatric patients with

polyarticular juvenile idiopathic arthritis. Published clinical studies evaluating the use of methotrexate in children and adolescents (i.e., patients 2 to 16 years of age) with pJIA demonstrated safety comparable to that observed in adults with rheumatoid arthritis. Otrexup does not contain a preservative. However, methotrexate injectable formulations containing the preservative benzyl alcohol are not recommended for use in neonates. There have been reports of fatal 'gasping syndrome' in neonates (children less than one month of age) following the administrations of intravenous solutions containing the preservative benzyl alcohol. Symptoms include a striking onset of gasping respiration, hypotension, bradycardia, and cardiovascular collapse. Serious neurotoxicity, frequently manifested as generalized or focal seizures, has been reported with unexpectedly increased frequency among pediatric patients with acute lymphoblastic leukemia who were treated with intermediate-dose intravenous methotrexate (1 gm/m^2).

Geriatric Use. Clinical studies of methotrexate did not include sufficient numbers of subjects age 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious reflecting the greater frequency of decreased hepatic and renal function, decreased folate stores, concomitant disease or other drug therapy (i.e., that interfere with renal function, methotrexate or folate metabolism) in this population. Since decline in renal function may be associated with increases in adverse reactions and serum creatinine measurements may overestimate renal function in the elderly, more accurate methods (i.e., creatinine clearance) should be considered. Serum methotrexate levels may also be helpful. Elderly patients should be closely monitored for early signs of hepatic, bone marrow and renal toxicity. In chronic use situations, certain toxicities may be reduced by folate supplementation. Post-marketing experience suggests that the occurrence of bone marrow suppression, thrombocytopenia, and pneumonitis may increase with age.

Renal Impairment. Methotrexate elimination is reduced in patients with impaired renal function. Such patients require especially careful monitoring for toxicity and require dose reduction or, in some cases, discontinuation of Otrexup administration.

Hepatic Impairment. The effect of hepatic impairment on methotrexate pharmacokinetics has not been studied. Otrexup is contraindicated in patients with alcoholic liver disease or other chronic liver disease. Patients with obesity, diabetes, hepatic fibrosis or steatohepatitis are at increased risk for hepatic injury and fibrosis secondary to methotrexate, and should be monitored closely.

OVERDOSAGE. Leucovorin is indicated to diminish the toxicity and counteract the effect of inadvertently administered overdosages of methotrexate. Leucovorin administration should begin as promptly as possible. As the time interval between methotrexate administration and leucovorin initiation increases, the effectiveness of leucovorin in counteracting toxicity decreases. Monitoring of the serum methotrexate concentration is essential in determining the optimal dose and duration of treatment with leucovorin. In cases of massive overdosage, hydration and urinary alkalinization may be necessary to prevent the precipitation of methotrexate and/or its metabolites in the renal tubules. Generally speaking, neither hemodialysis nor peritoneal dialysis has been shown to improve methotrexate elimination. However, effective clearance of methotrexate has been reported with acute, intermittent hemodialysis using a high-flux dialyzer (Wall, SM et al: *Am J Kidney Dis* 28(6):846-854, 1996). Accidental intrathecal overdosage may require intensive systemic support, high-dose systemic leucovorin, alkaline diuresis and rapid CSF drainage and ventriculolumbar perfusion. In postmarketing experience, overdose with methotrexate has generally occurred with oral and intrathecal administration, although intravenous and intramuscular overdose have also been reported. Reports of oral overdose often indicate accidental daily administration instead of weekly (single or divided doses). Symptoms commonly reported following oral overdose include those symptoms and signs reported at pharmacologic doses, particularly hematologic and gastrointestinal reaction. For example, leukopenia, thrombocytopenia, anemia, pancytopenia, bone marrow suppression, mucositis, stomatitis, oral ulceration, nausea, vomiting, gastrointestinal ulceration, gastrointestinal bleeding. In some cases, no symptoms were reported. There have been reports of death following overdose. In these cases, events such as sepsis or septic shock, renal failure, and aplastic anemia were also reported. Symptoms of intrathecal overdose are generally central nervous system (CNS) symptoms, including headache, nausea and vomiting, seizure or convulsion, and acute toxic encephalopathy. In some cases, no symptoms were reported. There have been reports of death following intrathecal overdose. In these cases, cerebellar herniation associated with increased intracranial pressure, and acute toxic encephalopathy have also been reported. There are published case reports of intravenous and intrathecal carboxypeptidase G2 treatment to hasten clearance of methotrexate in cases of overdose.

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FADONA's Mission: FADONA is the leading professional organization for current and aspiring leaders through professional development and networking, board certification and credentialing, and clinical expertise related to the care of patients/residents in the post-acute care continuum.

FADONA Vision: FADONA is the premier organization for the advancement of nursing executives and leaders to position them as key members of the health care leadership team addressing the constant evolving landscape and need for innovation in the post-acute care continuum.

Some key points that have an impact with long-term care nurses around the state:

FADONA is one of the largest and most active chapters of **NADONA**, the National Association of Directors of Nursing Administration/LTC.

FADONA/NADONA/LTC is the largest educational organization dedicated exclusively to nursing and administration professionals in long-term care and assisted living.

NADONA's motto is Education, Communication, Service. Everything done by the organization incorporates these elements.

FADONA is the only professional organization exclusively for and by long-term care (LTC) nurses in administration in Florida.

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FADONA members are highly flexible, highly trained, and very determined nurse leaders.

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FADONA continues to build the professional network — one step at a time.

Professional Certification, CDONA/LTC, is offered through NADONA.

Professional Standards that LTC nurse administrators are held to are set by NADONA. These standards embody the same elements as our motto.

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In 2009, "FADONA's Principles of Excellence for Florida Directors of Nursing & Nurse Administrators" was published to support the provision of long-term health care services that are desired, meaningful, successful, and efficient. They are intended to assist directors of nursing in achieving these objectives and to guide and inspire creative leadership in LTC.

The principles encourage the director of nursing to follow a reasonable course of action based on current knowledge, available resources, and the needs of the facility so that effective and safe care can be delivered. They are aspirational in nature and intended to foster self-appraisal and continuous performance improvement. The principles are neither inflexible rules nor requirements of practice.

These guiding principles feature FADONA's Mission & Vision, Culture of Quality, Resident Care & Quality-of-Life, Caregivers, and Staff Finance.

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2023 FADONA Convention Registration Form

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Name: _____ **Title:** _____

Checkoff all appropriate professions: __ **RN** , __ **LPN,** __ **NP,** __ **, NHA License #s:** _____ **State:** _____

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[ ] YES! Here are my 2023 FADONA Convention Registration Fees & Annual Membership Dues.

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1. **Early-Bird, Full Registration: *395** for members and **$445** for non-members on or before **Feb. 28, 2023**. $ _____
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2. **Preconvention Workshop (6 hours) on March 20** — Includes 6.0 CEUs, Lunch, and "Sparked" book by Jonathan Fields.
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5. **Fun Night** on **Wednesday, March 22:** Each paid Full-Registrant above receives one (1) ticket.
   Extra tickets for spouses or guests (this rate is not available to vendors or exhibitors)..... **$75** each $ _____

Total Amount Enclosed — Please use separate registration forms for each registrant..... $ _____

* **Full Registration Fees**: Includes attendance at all FADONA educational sessions starting with Session 102 on Monday, March 20, to Thursday, March 23, 2023; all planned meals and receptions; CEs/CEUs for Florida-licensed RNs, NPs, LPNs, and NHAs; Trade Show pass; one (1) ticket to Fun Night; and eligibility to win great door prizes. The Preconvention Workshop is extra. Register online at www.fadona.org/convention.html.

Handouts: Will be available at **www.fadona.org** at least **7-10 days** before the convention so you may print them without charge before you get to the convention. However, please be aware that we cannot ensure the availability of every PowerPoint presentation or handout for every session.

Refund/Cancellation Policy: All requests for attendee refunds must be made in writing and received on or before **March 1, 2023**. There will be a **$50** administrative fee on all attendee refunds. There will be no attendee refunds after **March 1, 2023**. Refund requests due to AHCA surveys will be given priority.

Returned-Check Policy: There is a **$35** charge for all checks returned from the bank.

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Hotel Reservations: Registration fee does not include hotel accommodations. Convention headquarters is at the **Rosen Plaza Hotel***: The special FADONA group rate is **$165** per single/double occupancy, no resort fee, and 50% discount off self-parking for overnight guests. Hotel will provide group rate for three (3) days pre- and three (3) days post-program dates, based on availability. Complimentary high-speed internet access in guest rooms and public spaces with basic wireless internet access in the assigned meeting rooms and pre-function areas.

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[1] Kumar, P., et al. (2017). Family perspectives on hospice care experiences of patients with cancer. *Journal of Clinical Oncology*, 35(4), 432.

[2] Teno, J. et al. (2007). Timing of referral to hospice and quality of care: length of stay and bereaved family members' perceptions of the timing of hospice referral. *Journal of Pain and Symptom Management*, 34(2), 120-125.

[3] Trella Health (2020). *Quantifying Hospice's End-of-Life Impact*. Available at: https://www.trellahealth.com/portfolio_page/ quantifying-hospices-end-of-life-impact/