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Janus Kinase (JAK) Inhibitors Used in the Treatment of Rheumatoid Arthritis (RA)

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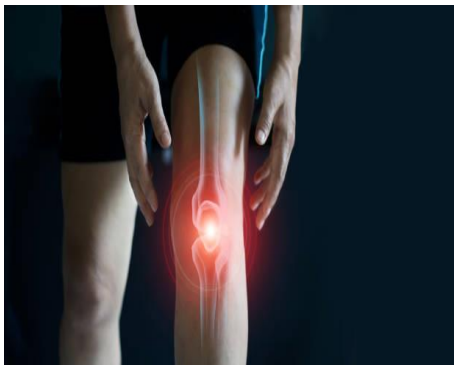
RA, an auto immune condition, causes chronic inflammation impacting joints which causes progressive damage to the synovium along with occasional effects on organ systems. It has negative effects on activities of daily living ranging from decreased range of motion to inability to walk often with increased pain. Increased fatigue is also common. Fortunately, multiple therapies are available which include disease modifying anti-rheumatic drugs (DMARDs) like methotrexate, hydroxychloroquine, or tumor necrosis factor (TNF) inhibitors like etanercept, infliximab, and other biologics. Most treatments for RA are delivered by intramuscular or subcutaneous injection or intravenous infusion. In 2012, the first Janus kinase (JAK) inhibitor, tofacitinib (Xeljanz) entered the market followed by baricitinib (Olumiant), and upadacitinib (Rinvoq). The advantage of these JAK inhibitors is that they are all oral medications.[1, 2]

JAK inhibitors block activity and response of Janus kinase enzymes (JAK1, JAK2, JAK3, and TYK2) which typically promote inflammation (Jamilloux #1 review). JAKs are intra cellular enzymes that mediate the signaling of cytokines and growth factors. JAK inhibitors bind and modulate the catalytic activity of JAKs which then blocks the inflammation of RA. [1, 3]

Generic Name	Brand Name	Manufacturer	Daily dose	Adjust dose	Contraindicated	Off-label use
Tofacitinib	Xeljanz (2012)	Pfizer	5mg bid OR 11mg XR daily	Renal or hepatic impairment	Combining with DMARDs	
Baricitinib	Olumiant (2018)	Lilly	2mg daily	Renal impairment	Combining with DMARDs	COVID-19
Upadacitinib	Rinvoq (2019)	AbbVie	15mg ER daily		Combining with DMARDs	



Side effects of tofacitinib include: upper respiratory tract infection, cardiovascular effects, gastrointestinal perforation, serious infections, ILD, malignancy, nasopharyngitis, diarrhea, bone marrow suppression, hyperlipidemia, and headache.[1] Side effects of upadactinib include: upper respiratory tract infections, neutropenia, lymphocytopenia, nausea, hepatotoxicity, CPK elevations, DVT, PE, increased cholesterol, and gastrointestinal perforation.[1] Side effects of baricitinib include: upper respiratory tract infections, herpes zoster infection, hepatotoxicity, hematologic toxicities including anemia, gastrointestinal perforations, thrombosis, lymphocytopenia, neutropenia, increase in SCR and CPK.[1] A 2016 study indicated that there is an increased possibility of gastrointestinal perforation in patients taking tofacitinib which may be more than double that of TNF inhibitors.[4] Note that this study was completed prior to upadactinib and baricitinib coming on the market.

Black box warning sample. A similar warning is required for Xeljanz and Rinvoq.

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

SERIOUS INFECTIONS

Patients treated with OLUMIANT are at risk for developing serious infections that may lead to hospitalization or death *[see Warnings and Precautions (5.1) and Adverse Reactions (6.1)]*. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

If a serious infection develops, interrupt OLUMIANT until the infection is controlled.

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before initiating OLUMIANT and during therapy. If positive, start treatment for latent infection prior to OLUMIANT use.**
- **Invasive fungal infections, including candidiasis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, and other infections due to opportunistic pathogens.**

The risks and benefits of treatment with OLUMIANT should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with OLUMIANT including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy *[see Warnings and Precautions (5.1)]*.

MORTALITY

In a large, randomized, post marketing safety study in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor comparing another Janus kinase (JAK) inhibitor to tumor necrosis factor (TNF) blockers, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor *[see Warnings and Precautions (5.2)]*.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with OLUMIANT. In RA patients treated with another JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer (NMSC)) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk *[see Warnings and Precautions (5.3)]*.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue OLUMIANT in patients that have experienced a myocardial infarction or stroke *[see Warnings and Precautions (5.4)]*.

THROMBOSIS

Thrombosis, including deep venous thrombosis and pulmonary embolism, has been observed at an increased incidence in patients treated with

OLUMIANT compared to placebo. In addition, there were cases of arterial thrombosis. Many of these adverse events were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid OLUMIANT in patients at risk. Patients with symptoms of thrombosis should discontinue OLUMIANT and be promptly evaluated. *[see Warnings and Precautions (5.5)]*.[5]

In conclusion, JAK inhibitors offer the advantage of oral dosing, most often once per day. There are some differences in the side effects between each of these medications. However, the FDA requires a black box warning for all of them.

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CDC Immunization Updates

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The CDC recently released updated schedule changes and guidance regarding immunizations. Modifications were made regarding the presentation of both the child/adolescent and adult immunization information by adding an appendix listing the contraindications and precautions for each vaccine type. This allowed for the condensation of the "Special Situations" sections. Additionally, a QR code linking to the schedule online has been added to the cover page.

In addition to the newly created appendices, both the child/adolescent and adult schedules required informational updates. The Child and Adolescent Immunization schedule changes focus on clarifications and additional use recommendations. The CDC has also developed Catch-Up guidance "job aids" to assist with interpreting child/adolescent immunization schedule. The Catch-up job aids may be accessed at https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html. Although the Adult Immunization schedule adjustments also focus on clarifications of and minor additions to previous recommendations, they do contain some significant changes that should be noted, particularly the pneumococcal, hepatitis B, and zoster vaccinations. A summary of the 2022 changes can be found in the charts provided.

For the most up-to-date information on recommended immunization schedules from the CDC, ACIP, AAP, AAFP, ACOG, ACP, and ACNM please download the CDC Vaccine Schedules app free for iOS and Android devices. https://www.cdc.gov/vaccines/schedules/hcp/schedule-app.html#download .

2022 Child and Adolescent Immunization Schedule Changes	
General	• An appendix listing the contraindications and precautions for each vaccine type in the child and adolescent schedule was added • QR code added to cover page that links to the schedule online
Dengue	• Guidance note added ○ Specific information for areas with endemic dengue and pre-vaccination laboratory testing
Hib	• Note revised ○ Now includes routine and catch-up vaccinations recommendations using Vaxelis®
Hepatitis A	• Note revised ○ Clarifies recommended age for routine vaccination
Hepatitis B	• Note revised ○ Clarifies the post-vaccination serologic testing and revaccination recommendation
HPV	• Note revised ○ Clarifies number of doses for people with immunocompromising conditions
Influenza	• "Special Situations" section note condensed ○ Contraindications and precautions have been moved to the newly created appendix
Meningococcal ACWY	• Note updated ○ MenACWY vaccines may be administered simultaneously with MenB vaccines if indicated, but at a different anatomic site, when feasible
MMR	• Note updated ○ Now includes recommendation information for use of MMRV
Varicella	• Note updated ○ Now includes recommendation information for use of MMRV

2022 Adult Immunization Schedule Changes	
General	• An appendix listing the contraindications and precautions for each vaccine type in the child and adolescent schedule was added • QR code added to cover page that links to the schedule online • Society for Healthcare Epidemiology of America (SHEA) added as an approving partner

Hepatitis B	• States the vaccine is universally recommended for all adults aged 19 through 59 years,
	  ○ The 2-, 3-, or 4- dose regimens are listed
	• Risk-based recommendations for adults 60 and older are listed
	  ○ Also noted that anyone aged 60 or older, even those who do not meet risk-based recommendations, may still receive the vaccine

HPV	• Minor language clarity changes in the "Routine Vaccination" and "Special Situations" sections
Influenza	• The language edited to clarify the age as "19 years or older," • A hyperlink to the 2021-2022 influenza recommendations and a bullet for the 2022-2023 influenza recommendations were added. • Contraindications and precautions for influenza vaccines were moved to the newly created appendix
Meningococcal	• Note added: ○ "MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, when feasible."
MMR	• The HIV infection bullet "Special Situation" section was amended to include CD4 percentages in addition to CD4
Pneumococcal	• The "Routine vaccination" section states anyone aged 65 or older "who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive 1 dose of PCV15 or 1 dose of PCV20. If PCV15 is used, this should be followed by a dose of PPSV23." • The "Special situations" section states that those "aged 19 through 64 years with certain underlying medical conditions or other risk factors who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive 1 dose of PCV15 or 1 dose of PCV20. If PCV15 is used, this should be followed by a dose of PPSV23." • Also included is guidance for dosing intervals between PCV15 and PPSV23 and for patients who have previously received PCV13 or PPSV23 in the past • All the underlying medical conditions/risk factors that make those aged 19 through 64 years eligible to receive pneumococcal vaccination are listed in notes at the end of the section
Varicella	• As with the MMR, the HIV infection bullet "Special Situation" section was amended to include CD4 percentages in addition to CD4

Zoster	• The pregnancy bullet "Special situations" section now states:
	  ○ "There is currently no ACIP recommendation for RZV use in pregnancy. Consider delaying RZV until after pregnancy."
	• The immunocompromising conditions bullet now states:
	  ○ "RZV is recommended for use in persons aged 19 years and older who are (or will be) immunodeficient or immunosuppressed because of disease or therapy."

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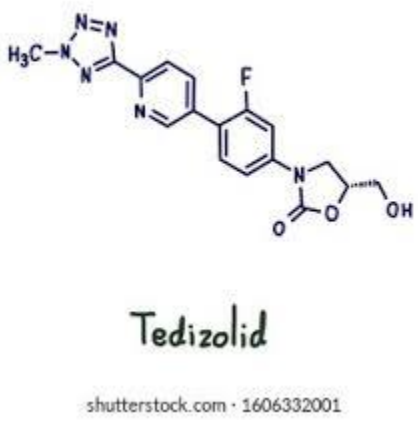
https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html (Accessed 3/25/2022)



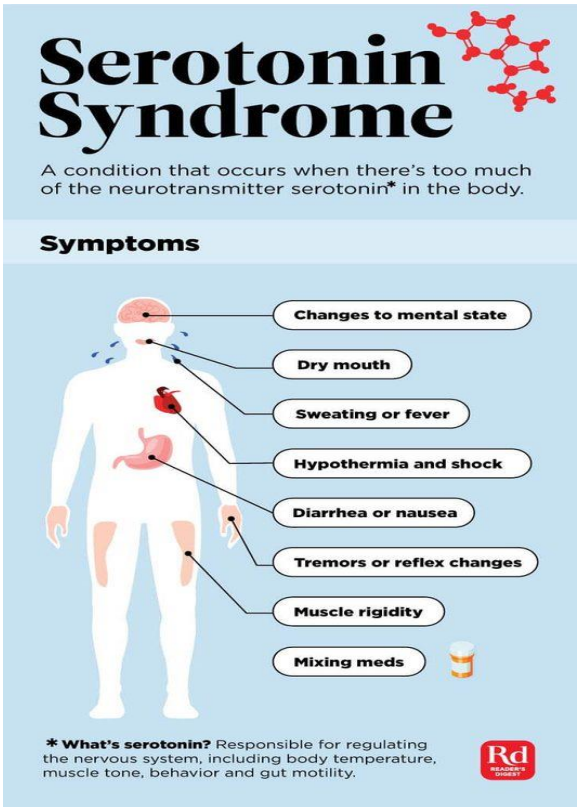


Photo By: Tatiana Ayazo/RD.com

Tedizolid and Serotonin Syndrome: Understudied or Non-existent?

Tyler B. Clay, PharmD, BCPS

The 1950's and 1960's were considered the "Golden Age" of antibiotic development. During this period, medicine gained over half of the antimicrobial classes used in practice today including quinolones, macrolides, glycopeptides, Nitrofurans, among others[1]. The approval of linezolid, a novel oxazolidinone antibiotic, in 2002 marks one of only a handful of new classes of antibiotics approved over the last 40 years[2]. The approval of linezolid made significant advancement in the treatment of methicillin resistant *staphylococcus aureus* (MRSA) and vancomycin resistant *enterococcus* (VRE), however it also carries a significant adverse effect profile including myelosuppression, peripheral neuropathy, and serotonin syndrome when combined with other serotonergic agents[3,4]. Linezolid is a relatively weak nonselective monoamine oxidase (MOA) inhibitor, however post market approval has demonstrated numerous reports of serotonin syndrome, particularly when the antimicrobial agent is co-administered with SNRI and SSRI antidepressants[5].

Following the publication of numerous case reports and the completion of a post-market analysis, an FDA safety announcement was released in in 2011 regarding the potentially life threatening reaction[6].

In 2014 a second oxazolidinone, tedizolid, was approved for the treatment of skins and soft tissue infections (SSTI's)[7]. Despite a similar adverse effect profile and theoretical MOA inhibition properties no FDA warnings surrounding the use of tedizolid, and other serotonergic agents is currently in place. This article will review the

current available literature on tedizolid and its potential for serotonergic toxicity.

The first clinical trial addressing the use of tedizolid was ESTABLISH-1, a phase 3 randomized, double blind, non-inferiority trial conducted in 2013 prior to FDA approval. The trial was designed to establish the non-inferiority of oral tedizolid vs oral linezolid in the treatment of SSTI's and compare the safety profiles of the two agents. A total of 667 patients were enrolled and followed over a period of eleven months. The trial found no significant differences between the two agents related to successful treatment of SSTI's or Treatment-Emergent Adverse Events (TEAEs), however it should be noted that no cases of central nervous toxicity was noted in either group[8]. ESTABLISH-2, published in 2014, was the second clinical trial addressing the clinical utility of tedizolid vs linezolid. ESTABLISH-2 was conducted in a similar design and patient population to ESTABLISH-1 except with intravenous infusions prior to oral therapy and found similar results with no cases of central nervous toxicity reported[9].

Following official FDA approval, a 2018 open label trial conducted in Japan by Mikamo et. al again assessed the safety profile of the two agents but included patients with SSTI related bacteremia competing longer treatment duration (up to 21 days). TEAE's were found to be numerically lower in the tedizolid treatment group but no statistical difference was observed[10]. These results were again repeated in a phase three clinical trial conducted in China, Taiwan, and the Philippines published in 2019[11].

Additional *in vitro* and *in vivo* studies have been completed to assess the potential for peripheral or central MOA inhibitor activity of tedizolid compared to linezolid. A meta-analysis of these studies found both agents display weak reversible MAO inhibitory activity, however the longer half-life of tedizolid (allowing once daily dosing compared to linezolid), tedizolids greater plasm protein binding, and minimal drug accumulation characteristics may lead to a reduced potential for central nervous system toxicity. [12]

Analyzing the current literature available, the verdict is still out on the potential for central nervous system toxicity associated tedizolid use. A 2021 systemic review of the FDA adverse event reporting system identified no significant safety signals, however the number of reports related to tedizolid compared to linezolid was limited (271 vs 11,259 respectively) and the authors concluded that the safety profile should continue to be tested through real-world dedicated studies.[13] Providers are encouraged to continue to examine the risk vs benefit profile on a case by case bases as the data continues to develop.

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Semglee®

Semglee®, the Face of Biosimilar Interchange

Kenneth Canipe PharmD, BCCCP

Therapeutic substitution has been a common practice throughout the United States with the guidance of the Orange Book, an FDA publication listing approved drug products with therapeutic equivalence evaluations.[13] However, the process of biosimilar agents is not quite as clear cut resulting in the creation of the Purple Book. The Purple book database contains information about FDA approved biological products including biosimilar and interchangeable biologicals.[11,12] As of May 2021, there were 29 FDA approved biosimilars, however none of them had an interchangeable designation.[10] On July 28th, 2021, the FDA approved the very first interchangeable biosimilar insulin product ever.[1]

Semglee® (insulin glargine) is a long acting insulin that is indicated for the treatment of type 1 diabetes mellitus and type 2 diabetes mellitus.[5] The use of insulin glargine is not new to the healthcare community as Lantus® (insulin glargine) was approved for use by the FDA on 4/20/2000, however what is new is the approval process for biosimilar agents. While both generic medications and biosimilars are approved through abbreviated pathways, that is where the similarities end.[3] Traditionally for a medication to achieve an AB equivalence designation via the Orange Book, a drug company had to submit a study that demonstrated bioequivalence to a reference listed drug product (i.e. the original medication to which a generic company is attempting to substitute).[6] This process is fairly straight forward and not as difficult for drug manufactures to pursue. The process for biosimilars, however is more complex in that the manufacture must prove that the biosimilar is highly similar to the reference product, in the case of Semglee® the reference product is Lantus®. Additionally, manufacturers must demonstrate that no difference exists between the reference product and the newly designed biosimilar.[2,3]

The therapeutic equivalence evaluations that were used to obtain interchangeability for Semglee® was a series of three trials (INSTRIDE 1, INSTRIDE2, and INSTRIDE 3). The INSTRIDE 1 trial utilized the primary endpoint of change in HbA1c from baseline to week 24.[7] It was a multicenter, open-label randomized trial that took place over 52 weeks and included 558 patients with type 1 diabetes. Patients were included in the trial if they were treated with once daily insulin glargine for more than 3 months and with a HbA1c≤9.5% at screening. In this trial, Semglee® was able to demonstrate non-inferiority to the reference insulin glargine (Lantus®).[7] The INSTRIDE 2 trial also had a primary endpoint based on change in HbA1c from baseline to week 24 similar to the INSTRIDE 1 trial.[8] The key difference between the two trials being that INSTRIDE 2 included 560 patients with type 2 diabetes mellitus. This study also demonstrated that Semglee® demonstrated comparable results to the reference insulin glargine product (Lanuts®).[8]

The trial that had the most impact regarding the FDA's interchangeability approval was the INSTRIDE 3 trial. This trial had a primary endpoint of change in HbA1c from baseline to week 36. It included patients who had successfully completed 52 weeks of the reference insulin glargine treatment in the INSTRIDE 1 study and provided written informed consent to patriciate in the INSTRDIE 3 trial.[9] There were a total of 127 patients included in this trial.[9] The patients were then divided into two groups, one of which continued the reference insulin glargine (Lantus®) for 36 weeks, and another group that would start on Semglee® for 12 weeks (week 0-12) before switching to the reference insulin glargine (Lantus®) for 12 weeks (week 12-24) and then back to Semglee® for another 12 weeks (week 24-36). The results of this trial demonstrated that both Semglee® and the reference insulin glargine resulted in equivalent efficacy and safety profiles, as well as demonstrating that the immunogenicity profiles were comparable between the two products.[9] The combination of these three trials ultimately lead to the decision of the FDA to designate Semglee® as the first FDA-approved interchangeable insulin glargine.

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