**Baricitinib (Lexi-Drugs)**

**ALERT: US Boxed Warning**

**Serious infections:**

Patients treated with baricitinib are at risk for developing serious infections that may lead to hospitalization or death. Most patients with rheumatoid arthritis who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. If a serious infection develops, interrupt baricitinib until the infection is controlled.

Reported infections include:

- Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Baricitinib should not be given to patients with active tuberculosis. Patients, except those with COVID-19, should be tested for latent tuberculosis before initiating baricitinib and during therapy. If positive, start treatment for latent infection prior to baricitinib 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 baricitinib 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 baricitinib including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

**Mortality:**

In a large, randomized, postmarketing safety study in rheumatoid arthritis (RA) patients ≥50 years of age with ≥1 cardiovascular risk factor comparing another Janus kinase (JAK) inhibitor to tumor necrosis (TNF) blockers, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor.

**Malignancies:**

Lymphoma and other malignancies have been observed in patients treated with baricitinib. In RA patients treated with another JAK inhibitor, a higher rate of malignancies (excluding nonmelanoma skin cancer) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk.

**Major adverse cardiovascular events:**
In RA patients ≥50 years of age with ≥1 cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (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 baricitinib in patients that have experienced a myocardial infarction or stroke.

**Thrombosis:**

Thrombosis, including deep venous thrombosis and pulmonary embolism, has been observed at an increased incidence in patients treated with baricitinib 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 with ≥1 cardiovascular risk factor treated with another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid baricitinib in patients at risk. Patients with symptoms of thrombosis should discontinue baricitinib and be promptly evaluated.

**Special Alerts**

**Janus Kinase Inhibitors Safety Review**

November 2022

Health Canada has previously communicated on the risks of major adverse cardiovascular events (MACE), thrombosis, malignancy, fatal events, and serious infections with the Janus kinase (JAK) inhibitor tofacitinib (Xeljanz/Xeljanz XR) and updated the Canadian product monograph to reflect these risks. Based on these safety findings and similar mechanisms of action to tofacitinib, Health Canada cannot rule out the risks of MACE, thrombosis (including fatal events), and malignancies for all other JAK inhibitors, including abrocitinib (Cibinqo), baricitinib (Olumiant), fedratinib (Inrebic), ruxolitinib (Jakavi), and upadacitinib (Rinvoq). Health Canada is working with manufacturers to update the Canadian product monographs for these products to include the risks of serious heart-related problems, fatal blood clots, and cancer, as a precautionary measure.


**Pronunciation**

(bar i SYE ti nib)

**Brand Names: US**

Olumiant

**Brand Names: Canada**

Olumiant

**Pharmacologic Category**
Antirheumatic, Disease Modifying; Antirheumatic, Miscellaneous; Janus Kinase Inhibitor

Dosing: Adult

Alopecia areata

Alopecia areata:

**Note:** Do not use in combination with other Janus kinase inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants; do not initiate in patients with an absolute lymphocyte count <500 cells/mm$^3$, ANC <1,000 cells/mm$^3$, or Hb <8 g/dL.

**Oral:** Initial: 2 mg once daily; if response is inadequate may increase to 4 mg once daily. For patients with nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss, consider initiating therapy with 4 mg once daily. In patients receiving 4 mg once daily (as initial therapy or after a dose increase), reduce dose to 2 mg once daily once an adequate response is achieved.

COVID-19, hospitalized patients

**COVID-19, hospitalized patients:**

**Note:** For use in hospitalized patients with significant oxygen requirements (eg, high-flow oxygen, noninvasive ventilation, mechanical ventilation, extracorporeal membrane oxygenation) and those with lower but increasing oxygen requirements and evidence of systemic inflammation ($^\text{Ref}$). Do not initiate if absolute lymphocyte count is <200 cells/mm$^3$ or if ANC is <500 cells/mm$^3$.

**Oral:** 4 mg once daily, as part of an appropriate combination regimen, for 14 days or until hospital discharge, whichever is first ($^\text{Ref}$).

Rheumatoid arthritis

**Rheumatoid arthritis:**

**Note:** For use as adjunctive therapy in patients who have not met treatment goals despite maximally tolerated methotrexate therapy; may also be used off-label as an alternative to methotrexate in disease-modifying antirheumatic drug (DMARD)–naïve patients with moderate to high disease activity ($^\text{Ref}$). Do not use in combination with biologic DMARDs or with strong immunosuppressants (eg, azathioprine, cyclosporine); do not initiate in patients with an absolute lymphocyte count <500 cells/mm$^3$, ANC <1,000 cells/mm$^3$, or Hb <8 g/dL.

**Oral:** 2 mg once daily.

**Dosage adjustment for concomitant therapy:** Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information.
* See Dosage and Administration in AHFS Essentials for additional information.

**Dosing: Older Adult**

Refer to adult dosing.

**Dosing: Altered Kidney Function: Adult**

The renal dosing recommendations are based upon the best available evidence and clinical expertise. Senior Editorial Team: Bruce Mueller, PharmD, FCCP, FASN, FNKF; Jason A. Roberts, PhD, BPharm (Hons), B App Sc, FSHP, FISAC; Michael Heung, MD, MS.

**Altered kidney function: Oral:**

**Alopecia areata:**

*If initial recommended dose is 2 mg once daily:*

- eGFR ≥60 mL/minute/1.73 m²: No dosage adjustment necessary.
- eGFR 30 to <60 mL/minute/1.73 m²: Reduce dose to 1 mg once daily.
- eGFR <30 mL/minute/1.73 m²: Use is not recommended.

*If initial recommended dose is 4 mg once daily:*

- eGFR ≥60 mL/minute/1.73 m²: No dosage adjustment necessary.
- eGFR 30 to <60 mL/minute/1.73 m²: Reduce dose to 2 mg once daily.
- eGFR <30 mL/minute/1.73 m²: Use is not recommended.

**COVID-19:**

- eGFR ≥60 mL/minute/1.73 m²: No dosage adjustment necessary.
- eGFR 30 to <60 mL/minute/1.73 m²: 2 mg once daily.
- eGFR 15 to <30 mL/minute/1.73 m²: 1 mg once daily.
- eGFR <15 mL/minute/1.73 m²: Use is not recommended.

**Rheumatoid arthritis:**

- eGFR ≥60 mL/minute/1.73 m²: No dosage adjustment necessary.
- eGFR 30 to <60 mL/minute/1.73 m²: 1 mg once daily.
- eGFR <30 mL/minute/1.73 m²: Use is not recommended.

**Hemodialysis, intermittent (thrice weekly):** Some removal possible based on drug characteristics (expert opinion): **Oral:** Use is not recommended (has not been studied) (manufacturer's labeling).

**Peritoneal dialysis:** Some removal possible based on drug characteristics (expert opinion): **Oral:** Use is not recommended (has not been studied) (manufacturer's labeling).
CRRT: Oral: Some removal possible based on drug characteristics (expert opinion): Use is not recommended (has not been studied) (expert opinion).

PIRRT (eg, sustained, low-efficiency diafiltration): Some removal possible based on drug characteristics (expert opinion): Oral: Use is not recommended (has not been studied) (expert opinion).

Dosing: Hepatic Impairment: Adult

Hepatic impairment prior to treatment initiation:

Alopecia areata or rheumatoid arthritis:
Mild to moderate impairment: No dosage adjustment necessary.
Severe impairment: Use is not recommended (has not been studied).

COVID-19:
Mild to moderate impairment: No dosage adjustment necessary.
Severe impairment: There are no dosage adjustments provided in the manufacturer’s labeling (has not been studied); use with caution and only if benefit outweighs risk.

Hepatotoxicity during treatment:
ALT/AST increased: If baricitinib-induced liver injury is suspected, interrupt therapy and further evaluate.

Dosing: Adjustment for Toxicity: Adult

Alopecia areata or rheumatoid arthritis:

Infection: If a patient develops a serious infection, interrupt treatment until the infection is controlled.

Lymphopenia:

Lymphopenia (absolute lymphocyte count [ALC] ≥500 cells/mm³): Maintain dose.
Lymphopenia (ALC <500 cells/mm³): Interrupt therapy until ALC ≥500 cells/mm³.

Neutropenia:

Neutropenia (ANC ≥1,000 cells/mm³): Maintain dose.
Neutropenia (ANC <1,000 cells/mm³): Interrupt therapy until ANC ≥1,000 cells/mm³.

Anemia:

Anemia (Hb ≥8 g/dL): Maintain dose.
Anemia (Hb <8 g/dL): Interrupt therapy until Hb ≥8 g/dL.

COVID-19:

Lymphopenia:
Lymphopenia (ALC ≥200 cells/mm³): Maintain dose.
Lymphopenia (ALC <200 cells/mm³): Interrupt therapy until ALC ≥200 cells/mm³.

Neutropenia:

Neutropenia (ANC ≥500 cells/mm³): Maintain dose.

Neutropenia (ANC <500 cells/mm³): Interrupt therapy until ANC ≥500 cells/mm³.

Dosing: Pediatric

COVID-19, treatment

COVID-19 (hospitalized patients), treatment: Very limited data available:

Note: The NIH states that data are insufficient to recommend for or against the use of baricitinib in pediatric patients (Ref). Pediatric dosing is based on ongoing clinical trials for other indications (Ref).

Children 2 to <9 years: Oral: 2 mg once daily for 14 days or until hospital discharge, whichever is first (Ref).

Children ≥9 years and Adolescents: Oral: 4 mg once daily for 14 days or until hospital discharge, whichever is first (Ref).

Dosage adjustment for concomitant therapy: Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information.

Dosage adjustment for toxicity: Children ≥2 years and Adolescents (Ref):

Absolute lymphocyte count (ALC) <200 cells/mm³: Consider interruption until ALC is ≥200 cells/mm³.

Absolute neutrophil count (ANC) <500 cells/mm³: Consider interruption until ANC ≥500 cells/mm³.

Dosing: Altered Kidney Function: Pediatric

COVID-19, treatment:

Acute kidney injury: Children ≥2 years and Adolescents: Not recommended (Ref).

Altered kidney function (Ref):

Children 2 to <9 years: Oral:

eGFR ≥60 mL/minute/1.73 m²: No dosage adjustment necessary.

eGFR 30 to <60 mL/minute/1.73 m²: 1 mg once daily.

eGFR <30 mL/minute/1.73 m²: Not recommended.

Children ≥9 years and Adolescents: Oral:

eGFR ≥60 mL/minute/1.73 m²: No dosage adjustment necessary.

eGFR 30 to <60 mL/minute/1.73 m²: 2 mg once daily.
eGFR 15 to <30 mL/minute/1.73 m²: 1 mg once daily.
eGFR <15 mL/minute/1.73 m²: Not recommended.

**Hemodialysis**: Children ≥2 years and Adolescents: Not recommended (Ref).

**Peritoneal dialysis**: Children ≥2 years and Adolescents: Not recommended (Ref).

**Dosing: Hepatic Impairment: Pediatric**

**COVID-19, treatment**: Children ≥2 years and Adolescents (Ref):

*Baseline hepatic impairment:*

Mild to moderate impairment: There are no dosage adjustments provided in the manufacturer-provided information.

Severe impairment: There are no dosage adjustments provided in the manufacturer-provided information (has not been studied); use recommended only if the potential benefit outweighs the potential risk; need for dosage modification is unknown.

*Hepatotoxicity during therapy (increases in ALT or AST and drug-induced liver injury is suspected):* Discontinue baricitinib until drug-induced liver injury is excluded.

**Use: Labeled Indications**

**Alopecia areata:** Treatment of severe alopecia areata in adults.

**COVID-19, hospitalized patients:** Treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.

**Rheumatoid arthritis:** Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor blockers.

Limitation of use: Use of baricitinib in combination with other Janus kinase inhibitors, biologic disease-modifying antirheumatic drugs, biologic immunomodulators, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

* See [Uses in AHFS Essentials](https://www.ahfsdr.com) for additional information.

**Clinical Practice Guidelines**

**COVID-19:**

IDSA, "[Guidelines on the Treatment and Management of Patients with COVID-19](https)"

NIH, "[Coronavirus Disease 2019 (COVID-19) Treatment Guidelines](https)"

**Rheumatoid Arthritis:**

ACR, “Guideline for the Treatment of Rheumatoid Arthritis,” [July 2021](https)

**Administration: Oral**
May be administered with or without food. For patients unable to swallow tablets whole, tablets may be dispersed in water. Place required number of tablets to achieve desired dose in a container with ~10 mL (minimum: 5 mL) of room temperature water; gently swirl the tablet(s) to disperse. Ensure tablets are sufficiently dispersed and immediately administer. Rinse container with an additional 5 to 10 mL of room temperature water and swallow. Tablets may be crushed to facilitate dispersion. According to the manufacturer, since it is not known if powder from the crushed tablets may pose a reproductive hazard to the preparer, if tablets are crushed, use proper control measures (eg, ventilated enclosure) or personal protective equipment (ie, N95 respirator).

Administration: Other

**Gastrostomy feeding tube (G tube):** Place required number of tablets to achieve desired dose in a container with ~15 mL (minimum: 10 mL) of room temperature water. Gently swirl the tablet(s) to disperse; ensure tablets are sufficiently dispersed to pass through syringe tip. Withdraw entire contents of container into an appropriate syringe and immediately administer through G tube. Rinse container with an additional ~15 mL (minimum: 10 mL) of room temperature water, withdraw contents into the syringe, and administer through G tube.

**Nasogastric or orogastric feeding tube (NG or OG tube):** Place required number of tablets to achieve desired dose in a container with ~30 mL of room temperature water. Gently swirl the tablet(s) to disperse; ensure tablets are sufficiently dispersed to pass through syringe tip. Withdraw entire contents of container into an appropriate syringe and immediately administer through enteral tube. For small tubes (<12 French), hold the syringe horizontally and shake during administration to avoid clogging of tube. Rinse container with a minimum of 15 mL of room temperature water, withdraw contents into the syringe, and administer through enteral tube.

Administration: Pediatric

**Oral:** Administer with or without food. If the 1 mg tablet is not available, the 2 mg tablet may be split along the longest diameter using a tablet splitter containing a razor blade; do not administer if tablet portions are unequal after splitting; store other half carefully to ensure breakage does not occur prior to the next dose (Ref). For patients who are unable to swallow whole tablets, tablets may be dispersed and administrated orally or via gastrostomy, nasogastric, or orogastric tube. Tablets may be crushed to facilitate dispersion; however, it is not known if powder from the crushed tablets may pose a reproductive hazard to the preparer; if tablets are crushed, use proper control measures (eg, ventilated enclosure) or personal protective equipment (ie, N95 respirator). After preparation, dispersed tablets should be administered immediately; however, the manufacturer indicates that dispersed tablets are stable in water for up to 4 hours.

*For patients unable to swallow tablets:* Place required number of tablets to achieve desired dose (up to 4 mg) in a container with ~10 mL (minimum: 5 mL) of room temperature water. Gently swirl the tablet(s) to disperse; immediately administer orally. Rinse container with an additional 10 mL (minimum: 5 mL) of room temperature water and administer entire contents orally to ensure entire dose is administered.

**Gastrostomy tube (G tube) administration:** Place required number of tablets to achieve desired dose (up to 4 mg) in a container with ~15 mL (minimum: 10 mL) of room temperature water. Gently swirl the tablet(s) to disperse; ensure tablets are sufficiently dispersed to pass through syringe tip. Withdraw
entire contents of container into an appropriate syringe and immediately administer through G tube. Rinse container with an additional ~15 mL (minimum: 10 mL) of room temperature water, withdraw contents into the syringe, and administer through G tube.

**Nasogastric or orogastric tube (NG or OG tube) administration:** Place required number of tablets to achieve desired dose (up to 4 mg) in a container with ~30 mL of room temperature water. Gently swirl the tablet(s) to disperse; ensure tablets are sufficiently dispersed to pass through syringe tip. Withdraw entire contents of container into an appropriate syringe and immediately administer through tube. For small tubes (<12 French), hold the syringe horizontally and shake during administration to avoid clogging of tube. Rinse container with a minimum of 15 mL of room temperature water, withdraw contents into the syringe, and administer through tube.

**Storage/Stability**

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

**Adult Patient Counseling**

**What is this drug used for?**

- It is used to treat rheumatoid arthritis.
- It is used in certain people to treat COVID-19.
- It is used to treat severe hair loss called alopecia areata.

**All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:**

For all uses of this drug:

- Signs of a common cold
- Upset stomach
- Cold sores

For alopecia areata:

- Headache
- Pimples (acne)
- Feeling tired or weak
- Stomach pain
- Weight gain
- Small red bumps on the skin
WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Infection like fever, chills, or sweating; cough; muscle aches; shortness of breath; more sputum or change in color of sputum; red, warm, swollen, painful, or blistered skin; weight loss; stomach pain; diarrhea; pain with passing urine or passing urine more often; or feeling tired or weak

- Heart attack, stroke, or blood clot like chest, throat, neck, or jaw tightness, pain, pressure, or heaviness; abnormal arm, back, neck, jaw, or stomach pain; coughing up blood; shortness of breath; cold sweats; severe upset stomach or throwing up; swelling, warmth, numbness, coldness, color change, or pain in a leg or arm; trouble speaking, swallowing, or thinking; weakness on 1 side of the body; change in balance; drooping on one side of the face; feeling lightheaded; or change in eyesight

- Change in color or size of a mole

- A skin lump or growth

- Feeling very tired or weak

- Shingles

- Dizziness or passing out

- Swollen gland, night sweats, shortness of breath, or weight loss without trying

- Swelling or pain in your stomach that is very bad, gets worse, or does not go away; throwing up blood or having throw up that looks like coffee grounds; upset stomach or throwing up that does not go away; or black, tarry, or bloody stools

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

Baricitinib FDA fact sheets – Health care provider; Patient

Note: This is not a comprehensive list of all side effects. Talk to your doctor if you have questions.

Consumer Information Use and Disclaimer: This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a limited summary of general information about the medicine’s uses from the patient education leaflet and is not intended to be comprehensive. This limited summary does NOT include all information available about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not intended to provide medical advice, diagnosis or treatment and does not replace information you receive from the healthcare provider. For a more detailed summary of information about the risks and benefits of using this medicine, please speak with your healthcare provider and review the entire patient education leaflet.

Medication Guide and/or Vaccine Information Statement (VIS)
An FDA-approved patient medication guide, which is available with the product information and as follows, must be dispensed with this medication:

Olumiant: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/207924s006lbl.pdf#page=26

**Contraindications**

There are no contraindications listed in the US manufacturer's labeling.

*Canadian labeling:* Additional contraindications (not in US labeling): Hypersensitivity to baricitinib or any component of the formulation.

**Warnings/Precautions**

*Concerns related to adverse effects:*

- GI perforations: Use with caution in patients at increased risk for GI perforation (eg, history of diverticulitis); perforations have been reported in clinical trials. Promptly evaluate new-onset abdominal symptoms in patients taking baricitinib.

- Hematologic toxicity: Hematologic toxicity, including lymphopenia, anemia, and neutropenia, may occur and is generally reversible and managed by treatment interruption. Do not initiate therapy in patients with alopecia areata or rheumatoid arthritis with an absolute lymphocyte count <500 cells/mm³, ANC <1,000 cells/mm³, or Hb<8 g/dL, or in patients with COVID-19 with an absolute lymphocyte count <200 cells/mm³ or ANC <500 cells/mm³. Monitor CBC at baseline and periodically thereafter.

- Hepatic effects: Increased incidence of liver enzyme elevation (≥5 × ULN for ALT and ≥10 × ULN for AST) was observed in patients taking baricitinib. Monitor LFTs as clinically indicated; interrupt therapy if LFTs are increased and drug-induced liver injury is suspected.

- Hypersensitivity: Hypersensitivity reactions (sometimes serious), including angioedema, urticaria, and rash, have occurred; discontinue therapy and evaluate cause for serious reactions.

- Infections: Patients receiving baricitinib are at increased risk for serious infections, which may result in hospitalization and/or fatality. Do not initiate baricitinib in patients with active, serious, or opportunistic infections, including localized infections. The most common serious infections reported included pneumonia, urinary tract infections, and herpes zoster infections, although other serious infections may occur. Reactivation of viral infections (eg, herpes zoster) was observed in clinical trials; the impact of baricitinib on chronic viral hepatitis reactivation is unknown. If a patient develops herpes zoster, interrupt therapy until episode is resolved. Consultation with a hepatologist may be necessary if hepatitis B virus DNA is detected. There are limited data available in patients with COVID-19 and concomitant active serious infections; consider risks and benefits of treatment.

- Lipid abnormalities: Dose-dependent increases in lipid parameters (eg, total, low-density lipoprotein, and high-density lipoprotein cholesterol) were observed in patients receiving baricitinib; maximum lipid increases were typically seen within 12 weeks of initiation. Assess lipids 12 weeks after baricitinib initiation and manage lipid abnormalities accordingly.
• Malignancy and lymphoproliferative disorders: Lymphoma and other malignancies have been observed in patients receiving baricitinib. A higher rate of lung cancers was observed in patients who smoke or have smoked receiving Janus kinase inhibitors, and these patients also had an additional increased risk of overall malignancies. Consider risks versus benefits prior to use or continuing therapy in patients with a known malignancy (other than successfully treated nonmelanoma skin cancers [NMSCs]), when continuing baricitinib in patients who develop a new malignancy, or in patients who smoke or have smoked. NMSCs have been reported.

• Tuberculosis: Tuberculosis (TB) (pulmonary or extrapulmonary) has been reported in patients receiving baricitinib. Use with caution in patients who have resided or traveled in regions where TB is endemic. Consider antituberculosis therapy if an adequate course of treatment cannot be confirmed in patients with a history of latent or active TB or for patients with risk factors despite negative skin test.

Other warnings/precautions:

• Immunizations: Immunization status should be current before initiating therapy in patients with rheumatoid arthritis. Live vaccines should not be given concomitantly with baricitinib; recommended interval between receipt of live vaccines and initiation of immunosuppressive agents such as baricitinib should follow current vaccination clinical guidelines.

* See Cautions in AHFS Essentials for additional information.

Older Adult Considerations

In clinical trials, no overall differences in safety or effectiveness were observed between older subjects and younger subjects. However, older adults are more likely to have decreased renal function and this medication is not recommended in patients with a GFR <60 mL/minute/1.73m². Therefore, renal function should be closely monitored and use of this medication in older adults may be limited.

Reproductive Considerations

Recommendations for use of baricitinib to treat rheumatic and musculoskeletal diseases in patients planning to become pregnant or who are planning to father a child are not available due to lack of data (ACR [Sammaritano 2020]). Consider discontinuing use 1 month prior to conception (Costanzo 2020).

Pregnancy Considerations

Placental transfer of baricitinib may be expected based on molecular weight (ACR [Sammaritano 2020]). Outcome data following baricitinib exposure in pregnancy are limited (Costanzo 2020; NIH 2022). Recommendations for use of baricitinib in pregnant patients with rheumatic and musculoskeletal diseases are not available due to lack of data (ACR [Sammaritano 2020]).

Baricitinib is a Janus kinase (JAK) inhibitor; use of a JAK inhibitor for the treatment of COVID-19 in pregnancy may be considered as part of a shared decision-making process when considering the potential benefits and possible risks (NIH 2022). The risk of severe illness from COVID-19 infection is increased in pregnant patients compared to nonpregnant patients. Pregnant and recently pregnant patients with moderate or severe infection are at increased risk of complications such as hypertensive disorders of pregnancy, postpartum hemorrhage, or other infections compared to pregnant patients.
without COVID-19. Pregnant patients with symptoms may require ICU admission, mechanical ventilation, or ventilatory support (ECMO) compared to symptomatic nonpregnant patients. Other adverse pregnancy outcomes include preterm birth and stillbirth. The risk of coagulopathy, cesarean delivery, and maternal death may be increased; neonates have an increased risk for NICU admission. Maternal age and comorbidities such as diabetes, hypertension, lung disease, and obesity may also increase the risk of severe illness in pregnant and recently pregnant patients (ACOG 2022; NIH 2022). Information related to the treatment of COVID-19 during pregnancy continues to emerge; refer to current guidelines for the treatment of pregnant patients.

Data collection to monitor pregnancy and infant outcomes following exposure to baricitinib is ongoing. Patients exposed to baricitinib during pregnancy are encouraged to notify the manufacturer (800-545-5979).

Data collection to monitor maternal and infant outcomes following exposure to COVID-19 during pregnancy is ongoing. Health care providers are encouraged to enroll patients exposed to COVID-19 during pregnancy in the Organization of Teratology Information Specialists (OTIS) pregnancy registry (877-311-8972; https://mothertobaby.org/join-study/).

Breastfeeding Considerations

It is not known if baricitinib is present in breast milk.

Due to the risk of serious adverse events in the breastfeeding infant, breastfeeding is not recommended by the manufacturer during therapy and for 4 days after the last dose of baricitinib. Recommendations for use of baricitinib in breastfeeding patients with rheumatic and musculoskeletal diseases are not available due to lack of data. Transfer into breast milk may be expected based on molecular weight (ACR [Sammaritano 2020]).


Briggs' Drugs in Pregnancy & Lactation

- **Baricitinib**

Adverse Reactions

The following adverse drug reactions and incidences are derived from product labeling unless otherwise specified. Reported adverse reactions are for adults.

**COVID-19, treatment:**

>10%: Hepatic: Increased serum alanine aminotransferase (≥3 x ULN: 18%), increased serum aspartate aminotransferase (≥3 x ULN: 12%)

1% to 10%:

Cardiovascular: Deep vein thrombosis (2%), pulmonary embolism (2%), septic shock (2%)
Genitourinary: Urinary tract infection (2%)
Hematologic & oncologic: Thrombocythemia (8%)
Respiratory: Pneumonia (3%)
<1%: Respiratory: Tuberculosis

**Alopecia areata/rheumatoid arthritis:**

>10%:
Infection: Infection (29%; serious infection: 1%)
Respiratory: Upper respiratory tract infection (16% to 21%)
1% to 10%:
Dermatologic: Acne vulgaris (≤6%), folliculitis (1% to 2%)
Endocrine & metabolic: Hyperlipidemia (4% to 6%), weight gain (≤2%)
Gastrointestinal: Abdominal pain (4%), nausea (2% to 3%)
Genitourinary: Genital candidiasis (1% to 2%), urinary tract infection (4%)
Hematologic & oncologic: Anemia (1%), neutropenia (1%)
Hepatic: Increased liver enzymes (≤3%; including increased gamma-glutamyl transferase, increased serum alanine aminotransferase, increased serum aspartate aminotransferase)
Infection: Herpes zoster infection (1%)
Nervous system: Fatigue (2%), headache (6% to 7%)
Neuromuscular & skeletal: Increased creatine phosphokinase in blood specimen (4%)
Respiratory: Lower respiratory tract infection (2%)
<1%:
Cardiovascular: Arterial thrombosis
Dermatologic: Fungal skin infection
Hematologic & oncologic: Lymphocytopenia, malignant lymphoma (B-cell), malignant neoplasm
Frequency not defined (any indication):
Endocrine & metabolic: Increased HDL cholesterol, increased LDL cholesterol, increased serum cholesterol, increased serum triglycerides
Gastrointestinal: Esophageal candidiasis
Infection: Bacterial infection, BK virus, candidiasis, cryptococcosis, cytomegalovirus disease, fungal infection, histoplasmosis, mycobacterium infection, opportunistic infection, viral infection
Renal: Increased serum creatinine
Respiratory: Infection due to an organism in genus *Pneumocystis*
Miscellaneous: Reactivation of disease (viral)
Postmarketing (any indication):
Cardiovascular: Acute myocardial infarction (FDA Safety Alert September 1, 2021), thrombosis (FDA Safety Alert September 1, 2021)
Gastrointestinal: Gastrointestinal perforation
Hematologic & oncologic: Skin carcinoma (nonmelanoma)
Hypersensitivity: Angioedema, hypersensitivity reaction
Nervous system: Cerebrovascular accident (FDA Safety Alert September 1, 2021)
Respiratory: Lung carcinoma (FDA Safety Alert September 1, 2021)
* See [Cautions in AHFS Essentials](#) for additional information.

**Metabolism/Transport Effects**

**Substrate** of BCRP/ABCG2, CYP3A4 (minor), OAT1/3, P-glycoprotein/ABCB1 (minor); **Note:** Assignment of Major/Minor substrate status based on clinically relevant drug interaction potential

**Drug Interactions Open Interactions**

**Note:** Interacting drugs may **not be individually listed below** if they are part of a group interaction (eg, individual drugs within "CYP3A4 Inducers [Strong]" are NOT listed). For a complete list of drug interactions by individual drug name and detailed management recommendations, use the Lexicomp drug interactions program by clicking on the "Open Interactions" button above.

5-Aminosalicylic Acid Derivatives: May enhance the myelosuppressive effect of Myelosuppressive Agents. *Risk C: Monitor therapy*

Abrocitinib: May enhance the immunosuppressive effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). *Risk X: Avoid combination*

Anifrolumab: Biologic Disease-Modifying Antirheumatic Drugs (DMARDs) may enhance the immunosuppressive effect of Anifrolumab. *Risk X: Avoid combination*

BCG (Intravesical): Myelosuppressive Agents may diminish the therapeutic effect of BCG (Intravesical). *Risk X: Avoid combination*

BCG Products: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of BCG Products. Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of BCG Products. *Risk X: Avoid combination*
Brincidofovir: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Brincidofovir. Risk C: Monitor therapy

Brivudine: May enhance the adverse/toxic effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). Risk X: Avoid combination

Chloramphenicol (Ophthalmic): May enhance the adverse/toxic effect of Myelosuppressive Agents. Risk C: Monitor therapy

Cladribine: May enhance the myelosuppressive effect of Myelosuppressive Agents. Risk X: Avoid combination

Cladribine: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Cladribine. Risk X: Avoid combination

CloZAPine: Myelosuppressive Agents may enhance the adverse/toxic effect of CloZAPine. Specifically, the risk for neutropenia may be increased. Risk C: Monitor therapy

Coccidioides immitis Skin Test: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the diagnostic effect of Coccidioides immitis Skin Test. Management: Consider discontinuing therapeutic immunosuppressants several weeks prior to coccidioides immitis skin antigen testing to increase the likelihood of accurate diagnostic results. Risk D: Consider therapy modification

Corticosteroids (Systemic): May enhance the immunosuppressive effect of Baricitinib. Management: The use of baricitinib in combination with potent immunosuppressants is not recommended. Doses equivalent to more than 2 mg/kg or 20 mg/day of prednisone (for persons over 10 kg) administered for 2 or more weeks are considered immunosuppressive. Risk D: Consider therapy modification

COVID-19 Vaccines: Baricitinib may diminish the therapeutic effect of COVID-19 Vaccines. Management: Rheumatology guidelines recommend holding baricitinib, tofacitinib, or upadacitinib for 1 to 2 weeks after vaccine administration as permitted by the underlying disease. Risk D: Consider therapy modification

Deferiprone: Myelosuppressive Agents may enhance the neutropenic effect of Deferiprone. Management: Avoid the concomitant use of deferiprone and myelosuppressive agents whenever possible. If this combination cannot be avoided, monitor the absolute neutrophil count more closely. Risk D: Consider therapy modification

Dengue Tetravalent Vaccine (Live): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Dengue Tetravalent Vaccine (Live). Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Dengue Tetravalent Vaccine (Live). Risk X: Avoid combination

Denosumab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Denosumab. Management: Consider the risk of serious infections versus the potential benefits of coadministration of denosumab and immunosuppressants. If combined, monitor for signs/symptoms of serious infections. Risk D: Consider therapy modification

Deucravacitinib: May enhance the immunosuppressive effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). Risk X: Avoid combination
Dipyrone: May enhance the adverse/toxic effect of Myelosuppressive Agents. Specifically, the risk for agranulocytosis and pancytopenia may be increased *Risk X: Avoid combination*

Fexinidazole: Myelosuppressive Agents may enhance the myelosuppressive effect of Fexinidazole. *Risk X: Avoid combination*

Filgotinib: May enhance the immunosuppressive effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). *Risk X: Avoid combination*

Immunosuppressants (Cytotoxic Chemotherapy): May enhance the immunosuppressive effect of Baricitinib. *Risk X: Avoid combination*

Immunosuppressants (Miscellaneous Oncologic Agents): May enhance the immunosuppressive effect of Baricitinib. *Risk X: Avoid combination*

Immunosuppressants (Therapeutic Immunosuppressant Agents): May enhance the immunosuppressive effect of Baricitinib. *Risk X: Avoid combination*

Influenza Virus Vaccines: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Influenza Virus Vaccines. Management: Administer influenza vaccines at least 2 weeks prior to initiating immunosuppressants if possible. If vaccination occurs less than 2 weeks prior to or during therapy, revaccinate 2 to 3 months after therapy discontinued if immune competence restored. *Risk D: Consider therapy modification*

Leflunomide: May increase the serum concentration of OAT1/3 Substrates (Clinically Relevant). *Risk C: Monitor therapy*

Methotrexate: May enhance the immunosuppressive effect of Baricitinib. Management: Concomitant use of baricitinib with high-dose or IV methotrexate is not recommended. Use with antirheumatic doses of methotrexate is permitted, and if combined, patients should be monitored for infection. *Risk D: Consider therapy modification*

Mumps- Rubella- or Varicella-Containing Live Vaccines: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Mumps- Rubella- or Varicella-Containing Live Vaccines. Specifically, the risk of vaccine-associated infection may be increased. *Risk X: Avoid combination*

Nadofaragene Firadenovec: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Nadofaragene Firadenovec. Specifically, the risk of disseminated adenovirus infection may be increased. *Risk X: Avoid combination*

Natalizumab: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Natalizumab. *Risk X: Avoid combination*

Nitisinone: May increase the serum concentration of OAT1/3 Substrates (Clinically Relevant). *Risk C: Monitor therapy*

Olaparib: Myelosuppressive Agents may enhance the myelosuppressive effect of Olaparib. *Risk C: Monitor therapy*
Pidotimod: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Pidotimod. **Risk C: Monitor therapy**

Pimecrolimus: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Pimecrolimus. **Risk X: Avoid combination**

Pneumococcal Vaccines: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Pneumococcal Vaccines. **Risk C: Monitor therapy**

Poliovirus Vaccine (Live/Trivalent/Oral): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Poliovirus Vaccine (Live/Trivalent/Oral). Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Poliovirus Vaccine (Live/Trivalent/Oral). **Risk X: Avoid combination**

Polymethylmethacrylate: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the potential for allergic or hypersensitivity reactions to Polymethylmethacrylate. Management: Use caution when considering use of bovine collagen-containing implants such as the polymethylmethacrylate-based Bellafill brand implant in patients who are receiving immunosuppressants. Consider use of additional skin tests prior to administration. **Risk D: Consider therapy modification**

Pretomanid: May increase the serum concentration of OAT1/3 Substrates (Clinically Relevant). **Risk C: Monitor therapy**

Probenecid: May increase the serum concentration of Baricitinib. Management: When baricitinib is combined with probenecid, reduce baricitinib 4 mg daily to 2 mg daily or reduce baricitinib 2 mg daily to 1 mg daily. Don’t use probenecid if recommended baricitinib dose is only 1 mg daily. **Risk D: Consider therapy modification**

Promazine: May enhance the myelosuppressive effect of Myelosuppressive Agents. **Risk C: Monitor therapy**

Rabies Vaccine: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Rabies Vaccine. Management: Complete rabies vaccination at least 2 weeks before initiation of immunosuppressant therapy if possible. If combined, check for rabies antibody titers, and if vaccination is for post exposure prophylaxis, administer a 5th dose of the vaccine. **Risk D: Consider therapy modification**

Ropeginterferon Alfa-2b: Myelosuppressive Agents may enhance the myelosuppressive effect of Ropeginterferon Alfa-2b. Management: Avoid coadministration of ropeginterferon alfa-2b and other myelosuppressive agents. If this combination cannot be avoided, monitor patients for excessive myelosuppressive effects. **Risk D: Consider therapy modification**

Ruxolitinib (Topical): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Ruxolitinib (Topical). **Risk X: Avoid combination**
Sipuleucel-T: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Sipuleucel-T. Management: Consider reducing the dose or discontinuing the use of immunosuppressants prior to initiating sipuleucel-T therapy. **Risk D: Consider therapy modification**

Tacrolimus (Topical): Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Tacrolimus (Topical). **Risk X: Avoid combination**

Talimogene Laherparepvec: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Talimogene Laherparepvec. Specifically, the risk of infection from the live, attenuated herpes simplex virus contained in talimogene laherparepvec may be increased. **Risk X: Avoid combination**

Taurursodiol: May increase the serum concentration of OAT1/3 Substrates (Clinically Relevant). **Risk X: Avoid combination**

Teriflunomide: May increase the serum concentration of OAT1/3 Substrates (Clinically Relevant). **Risk C: Monitor therapy**

Tertomotide: Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Tertomotide. **Risk X: Avoid combination**

Tofacitinib: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Tofacitinib. Management: Coadministration of tofacitinib with potent immunosuppressants is not recommended. Use with non-biologic disease-modifying antirheumatic drugs (DMARDs) was permitted in psoriatic arthritis clinical trials. **Risk X: Avoid combination**

Typhoid Vaccine: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Typhoid Vaccine. Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Typhoid Vaccine. **Risk X: Avoid combination**

Upadacitinib: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the immunosuppressive effect of Upadacitinib. **Risk X: Avoid combination**

Vaccines (Inactivated/Non-Replicating): Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Vaccines (Inactivated/Non-Replicating). Management: Give inactivated vaccines at least 2 weeks prior to initiation of immunosuppressants when possible. Patients vaccinated less than 14 days before initiating or during therapy should be revaccinated at least 2 to 3 months after therapy is complete. **Risk D: Consider therapy modification**

Vaccines (Live): May enhance the adverse/toxic effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). Specifically, the risk of vaccine-associated infection may be increased. Vaccines (Live) may diminish the therapeutic effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). **Risk X: Avoid combination**

Yellow Fever Vaccine: Immunosuppressants (Therapeutic Immunosuppressant Agents) may enhance the adverse/toxic effect of Yellow Fever Vaccine. Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Therapeutic Immunosuppressant Agents) may diminish the therapeutic effect of Yellow Fever Vaccine. **Risk X: Avoid combination**
**Monitoring Parameters**

In all patients: Lymphocyte, neutrophil, platelet counts, and Hb, LFTs, and renal function (baseline and periodically thereafter); signs/symptoms of infections (including tuberculosis) during and after therapy.

In patients with an anticipated long-term duration of therapy (eg, alopecia areata, rheumatoid arthritis): Lipids (12 weeks after therapy initiation and periodically thereafter); viral hepatitis (prior to initiating therapy in accordance with clinical guidelines); latent tuberculosis (prior to initiating therapy); abdominal symptoms (in patients at increased risk for GI perforation); skin examinations (periodically, in patients at increased risk for skin cancer).

**Advanced Practitioners Physical Assessment/Monitoring**

Obtain lymphocyte, neutrophil, platelet counts, hemoglobin, and liver function tests. Assess for viral hepatitis prior to therapy. Refer to dermatologist for periodic skin examinations while undergoing treatment. Order vaccinations the patient will need prior to initiating treatment. Assess other medicines patient may be taking, alternate therapy or dosage adjustments may be needed. Assess for signs of infection, thrombosis, and abdominal symptoms.

**Nursing Physical Assessment/Monitoring**

Check ordered labs and report any abnormalities. Monitor for and instruct patient to report signs and symptoms of infection, abdominal symptoms, or blood clots (pain, edema, or warmth in extremities, dyspnea, hemoptysis). Educate patients at risk of skin cancer on the importance of yearly skin checks. Instruct patients not to receive any vaccinations while receiving this medication.

**Dosage Forms: US**

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Tablet, Oral:

Olumiant: 1 mg, 2 mg, 4 mg [contains soybean lecithin]

**Dosage Forms: Canada**

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Tablet, Oral:

Olumiant: 2 mg [contains soybean lecithin]

**Anatomic Therapeutic Chemical (ATC) Classification**

- L04AA37

**Generic Available (US)**

No

**Pricing: US**
**Tablets (Olumiant Oral)**

1 mg (per each): $104.88

2 mg (per each): $104.88

4 mg (per each): $209.76

**Disclaimer:** A representative AWP (Average Wholesale Price) price or price range is provided as reference price only. A range is provided when more than one manufacturer’s AWP price is available and uses the low and high price reported by the manufacturers to determine the range. The pricing data should be used for benchmarking purposes only, and as such should not be used alone to set or adjudicate any prices for reimbursement or purchasing functions or considered to be an exact price for a single product and/or manufacturer. Medi-Span expressly disclaims all warranties of any kind or nature, whether express or implied, and assumes no liability with respect to accuracy of price or price range data published in its solutions. In no event shall Medi-Span be liable for special, indirect, incidental, or consequential damages arising from use of price or price range data. Pricing data is updated monthly.

**Mechanism of Action**

Baricitinib inhibits Janus kinase (JAK) enzymes, which are intracellular enzymes involved in stimulating hematopoiesis and immune cell function through a signaling pathway. In response to extracellular cytokine or growth factor signaling, JAKs activate signal transducers and activators of transcription (STATs), which regulate gene expression and intracellular activity. Inhibition of JAKs prevents the activation of STATs and reduces serum IgG, IgM, IgA, and C-reactive protein.

**Pharmacokinetics (Adult Data Unless Noted)**

Distribution: $V_d$: 76 L.

Protein binding: ~50% (plasma proteins); 45% (serum proteins).

Metabolism: Hepatic, primarily via CYP3A4.

Bioavailability: ~80%.

Half-life elimination: ~12 to 16 hours.

Time to peak: ~1 hour.

Excretion: Urine: ~75% (69% as unchanged drug); feces: ~20% (15% as unchanged drug).

**Pharmacokinetics: Additional Considerations (Adult Data Unless Noted)**

Altered kidney function: AUC increased by 1.41-, 2.22-, 4.05- and 2.41-fold for mild, moderate, and severe renal impairment, and ESRD (with hemodialysis), respectively.

Hepatic function impairment: For moderate hepatic impairment, AUC and $C_{max}$ increased by 1.19- and 1.08-fold, respectively.

**Dental: Local Anesthetic/Vasoconstrictor Precautions**
Prolongation of the EKG QT interval has been reported as a rare occurrence associated with other Janus kinase inhibitors (see ruxolitinib). Assuming the patient has no history of arrhythmia or not taking any medications which are associated with prolongation of the QT interval, there is nothing to suggest that baricitinib will increase the risk of an arrhythmia.

Dental Health Professional Considerations

The actions of baricitinib in treating rheumatoid arthritis is due to its ability to inhibit cytokines, including some in the interleukin family, from attaching to receptors that exacerbate arthritic symptoms. The receptors rely on the Janus kinase family of enzymes for receptor activations. These activations occur because the kinases phosphorylate receptor components (definition of kinases is enzymes that phosphorylate substrates). Janus kinases are members of the larger family of tyrosine kinases. Janus kinases, sometimes referred to as JAKs, due to the phosphorylation, recruit signal transducers and activators of transcription (STATs) which regulate intracellular activity. Drugs, such as baricitinib, that inhibit the activity of the Janus kinases block the receptor activations. Unfortunately, one undesired result is suppression of immune responses, leading to increased risk of infections. A US Boxed Warning reminds the clinician of the increased risk of serious infections in patients receiving baricitinib. Infections can often develop in patients receiving concomitant immunosuppressive agents, such as corticosteroids or methotrexate. It is suggested to closely monitor patients for the development of signs/symptoms of infection during and after baricitinib treatment.

Dental: Effects on Dental Treatment

Key adverse event(s) related to dental treatment: Opportunistic infections are possible; rare occurrence of esophageal candidiasis and fungal infections have been reported. Although there are no specific reports, patients may be at risk for candida albicans infections in the oral cavity.

Dental: Effects on Bleeding

Active therapy with immunosuppressants such as baricitinib may result in myelosuppression; medical consult suggested. Baricitinib labeling reports the occurrence of anemia and lymphocytopenia; rare occurrence of deep vein thrombosis.

Index Terms

Coronavirus; COVID-19

FDA Approval Date

June 01, 2018

Brand Names: International

Find brand name(s) by country

For country code abbreviations (show table)

References


Olumiant (baricitinib) [prescribing information]. Indianapolis, IN: Lilly USA LLC; June 2022.

Olumiant (baricitinib) [product monograph]. Toronto, Ontario, Canada: Eli Lilly Canada Inc; June 2022.


Refer to manufacturer's labeling.


US Food and Drug Administration (FDA). FDA Safety Alert. MedWatch. Xeljanz, Xeljanz XR (tofacitinib): FDA requires warnings about increased risk of serious heart-related events, cancer, blood clots, and death for JAK inhibitors that treat certain chronic inflammatory