Baricitinib

Indications/Dosage

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Labeled

- rheumatoid arthritis

Off-Label

- coronavirus disease 2019 (COVID-19) †
- severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection †

† Off-label indication

For the treatment of moderately to severely active rheumatoid arthritis in patients who have had an inadequate response to 1 or more tumor necrosis factor (TNF) antagonists

Oral dosage

- **Adults**

  2 mg PO once daily. May give with or without methotrexate or other non-biologic (conventional) disease-modifying antirheumatic drugs (DMARDs). Coadministration of certain drugs may need to be avoided or dosage adjustments may be necessary; review drug interactions. Use in combination with other Janus kinase (JAK) inhibitors, biologic or targeted DMARDs, or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.[63229]

INVESTIGATIONAL USE: For adjunctive use in the treatment of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection†, the virus that causes coronavirus disease 2019 (COVID-19)†

Oral dosage

- **Adults**

  Efficacy has not been established. Due to broad immunosuppressive effects, the National Institutes of Health (NIH) COVID-19 treatment guidelines recommend against the use of JAK inhibitors outside of clinical trials.[65314] Doses of 2 mg PO once daily for 10 to 14 days and 4 mg PO daily for 7 to 14 days are being evaluated in combination with antiviral therapy.[65192] [65205] [65253] [65254] [65346]

Therapeutic Drug Monitoring

Anemia

Determine hemoglobin concentration before baricitinib initiation, and do not start the drug in patients with a hemoglobin less than 8 grams/dL. Monitor the hemoglobin concentration according to routine patient management. For a hemoglobin concentration less than 8 grams/dL, interrupt baricitinib receipt until hemoglobin concentration is 8 grams/dL or more.[63229]

Lymphopenia

Determine absolute lymphocyte count (ALC) before baricitinib initiation, and do not start the drug in patients with an ALC less than 500 cells/mm^3. Monitor the ALC according to routine patient management. For an ALC less than 500 cells/mm^3, interrupt baricitinib receipt until ALC is 500 cells/mm^3 or more.[63229]

Neutropenia

Determine absolute neutrophil count (ANC) before baricitinib initiation, and do not start the drug in patients with an ANC less than 1,000 cells/mm^3. Monitor the ANC according to routine patient management. For an ANC less than 1,000 cells/mm^3, interrupt baricitinib receipt until ANC is 1,000 cells/mm^3 or more.[63229]

Serious Infection

Avoid use in patients with active, serious infection, including localized infections. If a serious infection occurs during treatment, hold baricitinib until the infection is controlled.[63229]

Lipid Elevations

Assess lipid profile approximately 12 weeks after initiation of baricitinib therapy. If elevations occur, manage patients according to clinical guidelines.[63229]

Maximum Dosage Limits

- Adults

  2 mg/day PO.

- Geriatric

  2 mg/day PO.

- Adolescents

  Safety and efficacy have not been established.

- Children

  Safety and efficacy have not been established.

- Infants

  Safety and efficacy have not been established.

- Neonates

  Safety and efficacy have not been established.

Patients with Hepatic Impairment Dosing

Mild or moderate impairment: No dosage adjustments needed.

Severe impairment: Not recommended.[63229]

Patients with Renal Impairment Dosing

eGFR more than 60 mL/minute/1.73 m^2: No dosage adjustment is needed.

eGFR 30 to 60 mL/minute/1.73 m^2: Reduce to 1 mg PO once daily.

eGFR less than 30 mL/minute/1.73 m^2: Use not recommended.[63229]

† Off-label indication

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References

63229 – Olumiant (baricitinib) tablets package insert. Indianapolis, IN: Lilly USA, LLC; 2019 Oct.

65192 – Barrett L. Treatment of moderate to severe coronavirus disease (COVID-19) in hospitalized patients. Retrieved April 2, 2020. Available on the World Wide Web at: https://clinicaltrials.gov/ct2/show/NCT04321993?cond=Coronavirus&intr=sarilumab&draw=2&rank=4.

65205 – Hospital of Prato. Baricitinib in symptomatic patients infected by COVID-19: an open-label, pilot study (BARI-COVID). Retrieved April 6, 2020. Available on the World Wide Web at: https://clinicaltrials.gov/ct2/show/NCT04320277?cond=COVID&intr=Baricitinib&draw=2&rank=1.

65253 – University of Colorado. Safety and efficacy of baricitinib for COVID-19. Retrieved April 14, 2020. Available on the World Wide Web at: https://clinicaltrials.gov/ct2/show/NCT04340232?cond=COVID&intr=Baricitinib&draw=2&rank=1.

65254 – Benfield T. Efficacy and safety of novel treatment options for adults with COVID-19 pneumonia (CCAP). Retrieved April 14, 2020. Available on the World Wide Web at:https://clinicaltrials.gov/ct2/show/NCT04345289?cond=COVID&intr=Baricitinib&draw=2&rank=4.

65314 – COVID-19 treatment guidelines panel. COVID-19 treatment guidelines. National Institutes of Health Web site. Accessed April 22, 2020. Available at: https://covid19treatmentguidelines.nih.gov/.

65346 – Cantini F, Niccoli L, Matarrese D, et al. Baricitinib therapy in COVID-19: A pilot study on safety and clinical impact. J Infect 2020 April 22;S0163-4453(20)30228-0. [Epub Ahead of Print]

How Supplied

Baricitinib Oral tablet
Olumiant 1mg Tablet (00002-4732) (Eli Lilly and Co)
Olumiant 2mg Tablet (00002-4182) (Eli Lilly and Co)

Description/Classification

Description

Baricitinib is an oral Janus kinase (JAK) inhibitor and is considered a targeted synthetic disease-modifying antirheumatic drug (tsDMARD). Janus kinases are intracellular enzymes that transmit signals arising from cytokine interactions on the cellular membrane to influence cellular processes of immune cell function. JAK inhibitors have been shown useful for a variety of inflammatory conditions. Baricitinib is indicated for adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to 1 or more tumor necrosis factor (TNF) inhibitors. For patients with rheumatoid arthritis (RA), baricitinib is used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs). Baricitinib improves RA symptoms and inhibits the radiographic progression of structural joint damage.[63229] Guidelines for RA were published before the availability of baricitinib, but the drug, like other tsDMARDs, is usually reserved for patients with contraindications, intolerance, or inadequate response to biologic agents such as the TNF inhibitors. The ideal combination of therapy for individual patients with inflammatory arthritis conditions such as RA is determined by treat to target strategies and severity of the

disease.[56233] The use of baricitinib does present some safety concerns. Serious infections and malignancy may be precipitated by JAK inhibitors; the drug is not to be used in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine. Also, JAK inhibitors have been associated with an increased risk of thrombosis.[63229]

Updates for coronavirus disease 2019 (COVID-19):

Based on preliminary data from a study of another immunomodulator (an IL-6 receptor antibody), studies have begun to evaluate the use of JAK inhibitors (including baricitinib) for the treatment of COVID-19.[65192][65205] [65253][65254][65346] However, due to the broad immunosuppressive effect, the National Institutes of Health (NIH) COVID-19 treatment guidelines recommend against the use of JAK inhibitors outside of clinical trials. [65314]

Classifications

- Musculo-Skeletal System
  - Antiinflammatory Agents and Antirheumatic Agents
    - Specific Anti-Rheumatic Agents
      - Other Specific Antirheumatics

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References

56233 – Singh JA, Furst DE, Bharat A, et al. 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care & Research 2012;64(5):625-639.

63229 – Olumiant (baricitinib) tablets package insert. Indianapolis, IN: Lilly USA, LLC; 2019 Oct.

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65205 – Hospital of Prato. Baricitinib in symptomatic patients infected by COVID-19: an open-label, pilot study (BARI-COVID). Retrieved April 6, 2020. Available on the World Wide Web at: https://clinicaltrials.gov/ct2/show/NCT04320277?cond=COVID&intr=Baricitinib&draw=2&rank=1.

65253 – University of Colorado. Safety and efficacy of baricitinib for COVID-19. Retrieved April 14, 2020. Available on the World Wide Web at: https://clinicaltrials.gov/ct2/show/NCT04340232?cond=COVID&intr=Baricitinib&draw=2&rank=1.

65254 – Benfield T. Efficacy and safety of novel treatment options for adults with COVID-19 pneumonia (CCAP). Retrieved April 14, 2020. Available on the World Wide Web at:https://clinicaltrials.gov/ct2/show/NCT04345289?cond=COVID&intr=Baricitinib&draw=2&rank=4.

65314 – COVID-19 treatment guidelines panel. COVID-19 treatment guidelines. National Institutes of Health Web site. Accessed April 22, 2020. Available at: https://covid19treatmentguidelines.nih.gov/.

65346 – Cantini F, Niccoli L, Matarrese D, et al. Baricitinib therapy in COVID-19: A pilot study on safety and clinical impact. J Infect 2020 April 22;S0163-4453(20)30228-0. [Epub Ahead of Print]

Administration Information

General Administration Information

For storage information, see the specific product information within the How Supplied section.

Route-Specific Administration

Oral Administration

Oral Solid Formulations

- Administer tablets with or without food.[63229]

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References

63229 – Olumiant (baricitinib) tablets package insert. Indianapolis, IN: Lilly USA, LLC; 2019 Oct.

Adverse Reactions

- abdominal pain
- acne vulgaris
- anemia
- candidiasis
- elevated hepatic enzymes
- GI perforation
- hepatotoxicity
- hypercholesterolemia
- hypertriglyceridemia
- infection
- laryngitis
- lymphoma
- lymphopenia
- nausea
- neutropenia
- new primary malignancy
- pharyngitis
- pulmonary embolism
- rhinitis
- sinusitis
- skin cancer
- thrombocytosis
- thromboembolism
- thrombosis
- tracheitis

Serious and sometimes fatal bacterial infection, mycobacterial infection, invasive fungal infection, viral infection, or infections due to other opportunistic pathogens have been reported in patients receiving baricitinib. The most commonly reported adverse reactions during baricitinib clinical trials for rheumatoid arthritis were upper respiratory tract infections (16.3% vs. 11.7% placebo). Included in upper respiratory tract infections were

acute sinusitis, sinusitis, acute tonsillitis, tonsillitis, epiglottitis, laryngitis, nasopharyngitis, oropharyngeal pain, pharyngitis, pharyngotonsillitis, rhinitis, sinobronchitis, and tracheitis. During the 16-week treatment period, overall infections were reported in 139 patients (99.1 events per 100 patient-years) treated with baricitinib 2 mg compared to 253 patients (82.1 events per 100 patient-years) receiving placebo. During 0 to 52-week exposure, infections were reported in 200 patients (59.6 events per 100 patient-years) receiving baricitinib 2 mg. During the 0 to 52 week exposure, the most commonly reported infections included viral upper respiratory infection, upper respiratory tract infection, urinary tract infection, and bronchitis. During the 16-week treatment period, serious infections were reported in 5 patients (3.6 events per 100 patient-years) receiving baricitinib 2 mg and in 13 patients (4.2 events per 100 patient-years) receiving placebo. During the 0 to 52 week exposure, serious infection was reported in 14 patients (4.2 events per 100 patient-years) receiving baricitinib 2 mg. The most common serious infections reported with baricitinib included pneumonia, herpes zoster, and urinary tract infections. Among opportunistic infections, tuberculosis, cryptococcosis, acute histoplasmosis, esophageal candidiasis, pneumocystosis, multidermatomal herpes zoster, cytomegalovirus infections, and BK virus were reported with baricitinib. During the 0 to 16 week treatment period, an opportunistic infection was reported in 2 placebo patients (0.6 events per 100 patient-years), no patients taking baricitinib 2 mg, and two patients taking baricitinib 4 mg (0.7 events per 100 patient-years); baricitinib 4 mg is not an FDA-approved dose. In the 0 to 52 week treatment period, opportunistic infections were reported in 1 patient (0.1 events per 100 patient-years) and 5 patients (0.6 per 100 patient-years) with baricitinib 2 mg and baricitinib 4 mg, respectively. Viral reactivation, including cases of herpes infection reactivation (e.g., herpes zoster), were observed in clinical studies. Herpes simplex and herpes zoster were reported in 0.8% and 1% of patients treated with baricitinib 2 mg, respectively compared to 0.7% and 0.4% of those receiving placebo, respectively. Included in herpes simplex were eczema herpeticum, genital herpes, ophthalmic herpes simplex, and oral herpes. If a patient develops herpes zoster, interrupt baricitinib therapy until the episode resolves. Baricitinib should not be administered to patients with active tuberculosis. Patients should be evaluated and tested for latent or active TB infection prior to and per applicable guidelines during baricitinib administration. There were no reported cases of tuberculosis during the 0 to 16 week treatment period. In the 0 to 52 week treatment period, tuberculosis was reported in 1 patient taking baricitinib 4 mg and 0 patients on baricitinib 2 mg. Cases of disseminated tuberculosis also were reported. Some patients have presented with disseminated rather than localized infection and were often taking concomitant immunosuppression agents such as methotrexate or corticosteroid therapy. Patients should be closely monitored for the development of signs and symptoms of infection during and after baricitinib treatment. Interrupt therapy with baricitinib if a patient develops a serious infection, an opportunistic infection, or sepsis. A patient who develops a new infection during treatment with baricitinib should undergo prompt and complete diagnostic testing appropriate for an immunocompromised patient; appropriate antimicrobial therapy should be initiated, and the patient should be closely monitored.[63229]

Hematologic laboratory abnormalities have been reported during baricitinib clinical trials. Neutropenia, defined as an absolute neutrophil count (ANC) below 1,000 cells/mm^3, was reported in 0.6% of patients receiving baricitinib 2 mg daily (none reported with placebo). ANC counts below 500 cells/mm^3 were not reported in any treatment group. Avoid or interrupt baricitinib treatment in patients with an ANC less than 1,000 cells/mm^3. Anemia, defined as hemoglobin less than 8 grams/dL, was reported during baricitinib clinical trials. Avoid or interrupt treatment in patients with a hemoglobin less than 8 grams/dL. Lymphopenia, defined as absolute lymphocyte count (ALC) less than 500 cells/mm^3 was reported during baricitinib clinical trials. Lymphocyte counts less than the lower limit of normal were associated with infection in patients treated with baricitinib but not in those receiving placebo. Avoid or interrupt baricitinib treatment in patients with an ALC less than 500 cells/mm^3. Increases in platelet counts (thrombocytosis) above 600,000 cells/mm^3 were reported in 1.1% of patients receiving 2 mg/day baricitinib and 1.1% in those receiving placebo. After 16 weeks of treatment, the mean platelet count increased by 3,000 cells/mm^3 in patients receiving placebo and by 15,000 cells/mm^3 in patients treated with baricitinib 2 mg.[63229]

Serious and even fatal venous thromboembolism, including deep venous thrombosis (DVT) and pulmonary embolism (PE), have been reported during baricitinib clinical trials. During the 16-week treatment period, DVT or PE was reported in 5 patients (1.7 events per 100 patient-years) receiving 4 mg daily (not an FDA approved dose); DVT or PE was not reported in those receiving placebo or 2 mg daily. Arterial thrombosis during the 16

week treatment period was reported in 1 patient receiving placebo (0.3 events per 100 patient-years), 2 patients receiving baricitinib 2 mg (1.4 events per 100 patient-years) and 2 patients (0.7 events per 100 patient-years) receiving baricitinib 4 mg per day. During the 0 to 52 week treatment period, venous thromboses were reported in 2 patients (0.6 events per 100 patient-years) receiving 2 mg per day and 7 patients (0.8 events per 100 patient-years) receiving 4 mg per day. Arterial thromboses were reported in 3 patients (0.9 events per 100 patient-years) receiving baricitinib 2 mg/day and 3 patients (0.3 events per 100 patient-years) receiving 4 mg/day. Baricitinib may cause increases in platelet counts (thrombocytosis). There is no clear relationship between platelet count elevations and thrombotic events. If signs and symptoms of DVT, PE, or arterial thrombosis occur, promptly evaluate and treat patients.[63229]

During baricitinib clinical trials, nausea was reported in 2.7% of patients receiving baricitinib 2 mg and at rates greater than with placebo. Gastrointestinal (GI) serious reactions, such as GI perforation, have been noted among baricitinib recipients, although the role of the drug in these events is unknown. Promptly evaluate patients presenting with new-onset abdominal symptoms, such as abdominal pain, for early identification of GI perforation. Cautious use of baricitinib is advised for patients who may be at increased risk for GI perforation. [63229]

Elevated hepatic enzymes have been reported in clinical trials with the use of baricitinib. Among patients receiving baricitinib 2 mg during a 16-week treatment period, alanine aminotransferase (ALT) elevations 3 times the upper limit of normal (ULN) or greater occurred in 1.7% of patients (vs. 1% placebo) and aspartate aminotransferase (AST) elevations 3 times the ULN or greater were reported in 1.3% of patients (vs. 0.8% placebo). Increases 5-times the ULN or more and 10-times the ULN or more were observed for both ALT and AST in patients in clinical trials. Prompt investigation of the cause of hepatic enzyme elevation is recommended to identify potential cases of drug-induced liver injury. If increases are observed and drug-induced hepatotoxicity is suspected, interrupt baricitinib treatment until this diagnosis is excluded.[63229]

During baricitinib clinical trials, dose-related increases in lipid parameters were reported. Elevations were observed at 12 weeks and remained stable thereafter. In patients treated with baricitinib 2 mg for 12 weeks, mean LDL cholesterol, mean HDL cholesterol, and mean triglycerides increased by 8 mg/dL, 7 mg/dL, and 7 mg/dL, respectively. The mean LDL/HDL ratio remained stable. Manage patients according to clinical guidelines for the management of hyperlipidemia, hypercholesterolemia or hypertriglyceridemia as per standards of care. Other laboratory alterations have been reported. Baricitinib treatment was associated with increases in creatine phosphokinase (CPK) within one week of starting the drug, but the CPK elevation leveled off after 8 to 12 weeks. At 16 weeks, the mean change in CPK for baricitinib 2 mg/day was 37 International Units/L. In controlled clinical trials, dose-related increases in serum creatinine (SCr) were also observed; at 52 weeks, the mean increase in SCr was less than 0.1 mg/dL with baricitinib 4 mg (non-FDA-approved dose). The clinical significance of the observed SCr increases is unknown.[63229]

Acne vulgaris was reported in less than 1% of patients receiving baricitinib during clinical trials.[63229]

Baricitinib may cause a new primary malignancy; malignancies were reported during clinical trials. During the 16-week treatment period, 1 patient (0.7 events per 100 patient-years) receiving baricitinib 2 mg per day developed a malignancy other than non-melanoma skin cancer (NMSC); no events were reported in the placebo group. Lymphoma and other cancers have been observed in patients taking baricitinib. During the 0 to 52 week treatment period, malignancies other than NMSC were reported in 2 patients (0.6 events per 100 patient-years) receiving baricitinib 2 mg per day. NMSC has also been reported in patients treated with baricitinib. Periodic skin evaluations are recommended for patients at an increased risk of skin cancer. Consider the risks and benefits of baricitinib when considering the continuation of the drug in patients who develop a malignancy.[63229]

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References

63229 – Olumiant (baricitinib) tablets package insert. Indianapolis, IN: Lilly USA, LLC; 2019 Oct.

Contraindications/Precautions

Absolute contraindications are italicized.

- anemia
- breast-feeding
- children
- corticosteroid therapy
- diabetes mellitus
- diverticulitis
- fungal infection
- geriatric
- GI perforation
- hepatic disease
- hepatitis
- hepatitis C infection
- herpes infection
- human immunodeficiency virus (HIV) infection
- hypercholesterolemia
- hyperlipidemia
- immunosuppression
- infants
- infection **B**
- lymphoma
- neutropenia
- new primary malignancy **B**
- pregnancy
- pulmonary disease
- renal failure
- renal impairment
- skin cancer
- thrombocytosis
- thromboembolic disease
- thromboembolism **B**
- thrombosis
- tuberculosis
- vaccination
- viral infection

Avoid use of baricitinib in patients with an active, serious infection, including localized infections. Serious and sometimes fatal bacterial infection, mycobacterial infection, invasive fungal infection, viral infection, or infections due to other opportunistic pathogens have been reported in rheumatoid arthritis patients receiving baricitinib. The risks and benefits of treatment should be considered prior to initiating baricitinib in patients: 1) with chronic or recurrent infection; 2) who have been exposed to tuberculosis; 3) with a history of a serious or an opportunistic infection; 4) who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or 5) with underlying conditions that may predispose them to infection (e.g., diabetes mellitus, human immunodeficiency virus (HIV) infection, chronic pulmonary disease, low lymphocyte counts, and pre-existing immunosuppression). The most common serious infections reported with baricitinib included pneumonia, herpes zoster, and urinary tract infections. Among opportunistic infections, tuberculosis, cryptococcosis, acute histoplasmosis, esophageal candidiasis, pneumocystosis, multidermatomal herpes zoster, cytomegalovirus infections, and BK virus were reported with baricitinib. Some patients have presented with disseminated rather than localized disease, and were often taking concomitant immunosuppression agents such as methotrexate or corticosteroid therapy. Ask patients if they have lived or have traveled to the Ohio and Mississippi River valleys or the Southwest because of an increased chance of acquiring certain kinds of fungal infections such as histoplasmosis, coccidioidomycosis, or blastomycosis. Viral reactivation, including cases of herpes infection reactivation (e.g., herpes zoster), were observed in clinical studies. If a patient develops herpes zoster, interrupt baricitinib therapy until the episode resolves. Carefully consider the risks and benefits of baricitinib before starting the drug in patients who have been exposed to tuberculosis (TB). Baricitinib should not be administered to patients with active tuberculosis. Patients should be evaluated and tested for latent or active TB infection prior to and per applicable guidelines during baricitinib administration. Consider anti-tuberculosis therapy before baricitinib administration in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed and for patients with a negative test for latent tuberculosis but who have risk factors for tuberculosis infection. Consultation with a physician with expertise in the treatment of tuberculosis is recommended to aid in the decision about whether initiating anti-tuberculosis therapy is

appropriate for an individual patient. Monitor patients for the development of signs and symptoms of tuberculosis in all patients during treatment. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with baricitinib. Therapy with baricitinib should be interrupted if a patient develops a serious infection, an opportunistic infection, or sepsis. A patient who develops a new infection during treatment with baricitinib should undergo prompt and complete diagnostic testing appropriate for an immunocompromised patient; appropriate antimicrobial therapy should be initiated, and the patient should be closely monitored.[63229]

Perform screening for viral hepatitis in accordance with clinical guidelines before starting therapy with baricitinib. The impact of baricitinib on chronic viral hepatitis reactivation is unknown. Patients with evidence of active hepatitis B or hepatitis C infection were excluded from clinical trials. Patients who were positive for hepatitis C antibody but negative for hepatitis C virus RNA were permitted to enroll. Patients with positive hepatitis B surface antibody and hepatitis B core antibody, without hepatitis B surface antigen, were permitted to enroll; such patients should be monitored for expression of hepatitis B virus (HBV) DNA. Should HBV DNA be detected, consult with a hepatologist. Use baricitinib with caution in any other patient with hepatic disease or impairment. Baricitinib is not recommended for patients with severe hepatic impairment. Increases in liver enzymes of 5 times and up to 10 times the upper limit of normal (ULN) were reported for both ALT and AST in clinical trials. Liver function tests (LFTs) should be evaluated at baseline and thereafter according to routine patient management. If increases in ALT or AST are seen and drug-induced liver toxicity is suspected, interrupt baricitinib treatment until drug-induced toxicity is excluded.[63229]

Determine neutrophil and lymphocyte counts before baricitinib initiation. Do not start the drug in patients with an absolute lymphocyte count (ALC) less than 500 cells/mm^3 or in patients with absolute neutrophil count (ANC) less than 1,000 cells/mm^3. Baricitinib may cause lymphopenia and neutropenia. Monitor the ANC and ALC periodically during baricitinib treatment according to routine patient management. Interrupt treatment in patients with an ANC less than 1,000 cells/mm^3 or an ALC less than 500 cells/mm^3 until the counts have recovered to amounts equal to or above these thresholds.[63229]

Determine the hemoglobin concentration before baricitinib initiation, and do not start the drug in patients with anemia defined as hemoglobin less than 8 grams/dL. Baricitinib may cause anemia. For patients who have hemoglobin 8 grams/dL or greater, monitor the hemoglobin concentration according to routine patient management. Treatment with baricitinib should be interrupted in patients who develop hemoglobin levels less than 8 grams/dL until the hemoglobin has recovered to 8 grams/dL or higher.[63229]

Baricitinib may increase the risk for a new primary malignancy. Consider the risks and benefits of baricitinib prior to initiating therapy in patients with a known cancer other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing the drug in patients who develop a malignancy. Lymphoma and other cancers have also been observed in patients taking baricitinib. NMSCs have also been reported in patients treated with baricitinib. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.[63229]

Use baricitinib with caution in patients with thromboembolic disease or who are at an increased risk of thromboembolism. Serious and even fatal venous thromboembolism, including deep venous thrombosis (DVT) and pulmonary embolism (PE), have been reported at an increased rate in patients treated with baricitinib compared to placebo. In addition, arterial thrombosis events in the extremities have been reported in clinical studies; many of these adverse events were serious and some resulted in death. Baricitinib may cause increases in platelet counts (thrombocytosis). There is no clear relationship between platelet count elevations and thrombotic events. If signs and symptoms of DVT, PE, or arterial thrombosis occur, promptly evaluate and treat patients.[63229]

Use baricitinib with caution in patients with renal impairment. Dosage reductions are recommended in patients with an estimated glomerular filtration rate (eGFR) of 30 to 60 mL/minute/1.73 m^2. Baricitinib is not recommended in patients with renal failure or an eGFR less than 30 mL/minute/1.73 m^2.[63229]

Update immunizations in agreement with current immunization guidelines prior to initiating baricitinib therapy. Patients who are taking baricitinib should not receive vaccination with live vaccines. These patients may receive non-live vaccines during baricitinib therapy. The interval between live vaccinations and the initiation of baricitinib therapy should be in accordance with current vaccination guidelines regarding immunosuppressive agents.[63229]

Cautious use of baricitinib is advised for patients who may be at increased risk for gastrointestinal (GI) perforation (e.g., patients with a history of diverticulitis). GI perforation has been noted among baricitinib recipients, although the role of baricitinib in these events is not known. Patients presenting with new onset abdominal symptoms should be evaluated promptly for early identification of GI perforation.[63229]

Use baricitinib with caution in patients with hyperlipidemia or hypercholesterolemia. Treatment with baricitinib was associated with increases in lipid parameters including total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. Assessment of lipid parameters in all patients should be performed approximately 12 weeks following initiation of baricitinib therapy. Manage patients according to clinical guidelines for the management of hyperlipidemia.[63229]

During clinical trials, no overall differences in safety or effectiveness were noted between geriatric and younger adult patients receiving baricitinib. However, greater sensitivity of some older individuals cannot be ruled out. Baricitinib is extensively excreted by the kidney, and the risk of adverse reactions may be greater for patients with impaired renal function. Geriatric patients are more likely to have decreased renal function; therefore, cautious dose selection and monitoring of renal function may be warranted in geriatric patients.[63229]

Sufficient data are not available to inform a drug-associated risk for major birth defects or miscarriage with the use of baricitinib during human pregnancy. In embryofetal animal studies, oral administration to rats and rabbits at exposures greater than 20 and 84 times the maximum recommended human dose (MRHD), respectively, resulted in reduced fetal body weights, increased embryolethality (rabbits only), and dose-related increases in skeletal malformations. Developmental toxicity was not observed in pregnant rats and rabbits treated with baricitinib at approximately 5 and 13 times the MRHD, respectively. In a pre- and post-development study in pregnant rats, oral baricitinib administration at exposures approximately 43 times the MRHD resulted in a reduction in pup viability, decreased fetal birth weight, reduced fetal body weight gain, decreased cytotoxic T cells on post-natal day 35 with no evidence of recovery by day 65, and developmental delays that might be attributable to decreased body weight gain. No developmental toxicity was observed at exposures approximately 9 times the MRHD.[63229]

Because of the potential for serious adverse reactions in a nursing infant, breast-feeding during baricitinib therapy is not recommended. No data are available on the presence of baricitinib in human milk, the effects of the drug on the breast-fed infant, or the effects on milk production. Baricitinib is present in the milk of lactating rats; the clinical relevance of this to human lactation is not known.[63229] Etanercept and infliximab may be potential alternatives to consider during breast-feeding. However, assessment of indication and patient-specific factors should be performed before considering an alternative agent.[61808] [62180]

The safety and efficacy of baricitinib in infants, children, and adolescents under the age of 18 years have not been established.[63229]

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References

61808 – Mahadevan U, McConnell RA, Chambers C. Drug safety and risk of adverse outcomes for pregnant patients with inflammatory bowel diseases. Gastroenterology. 2017;152:451-62.e2.

62180 – Gotestam Skorpen C, Hoeltzenbein M, Tincani A, et al. The EULAR points to consider for use of antirheumatic drugs before pregnancy, and during pregnancy and lactation. Ann Rheum Dis. 2016;75:795-810.

63229 – Olumiant (baricitinib) tablets package insert. Indianapolis, IN: Lilly USA, LLC; 2019 Oct.

Mechanism of Action

Baricitinib is an oral Janus kinase (JAK) inhibitor. Janus kinases are intracellular enzymes that transmit signals arising from cytokine or growth factor receptor interactions on the cellular membrane to influence cellular processes of immune cell function and hematopoiesis. JAK-mediated signaling is pivotal in immune activation, as cytokine receptors are expressed on most immune cells. Within the signaling pathway, JAKs phosphorylate and activate signal transducers and activators of transcription proteins (STATs), which modulate intracellular activity including gene expression. Baricitinib modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs. Cytokine signaling is transmitted through pairing of JAKs such as JAK1/JAK2, JAK1/JAK3, JAK1/TYK2, JAK2/JAK2, and JAK2/TYK2. Baricitinib has greater affinity for JAK1, JAK2, and TYK2, relative to JAK3. In human leukocytes, baricitinib inhibits cytokine-induced STAT phosphorylation mediated by JAK1/JAK2, JAK1/JAK3, JAK1/TYK2, or JAK2/TYK2 with comparable potencies. However, the relevance of specific JAK combinations to therapeutic effectiveness is not known. [63229]

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References

63229 – Olumiant (baricitinib) tablets package insert. Indianapolis, IN: Lilly USA, LLC; 2019 Oct.

Pharmacokinetics

Baricitinib is administered orally. After intravenous administration, the volume of distribution is 76 L, indicating the distribution of baricitinib into tissues. Plasma and serum protein bindings are approximately 50% and 45%, respectively. Approximately 6% of the orally administered baricitinib dose is identified as metabolites (3 from urine and 1 from feces), with CYP3A4 identified as the main metabolizing enzyme. No metabolites of baricitinib were quantifiable in plasma. In a clinical pharmacology study, approximately 75% of the administered dose was eliminated in the urine, while about 20% of the dose was eliminated in the feces. Baricitinib is predominately excreted as unchanged drug in the urine (69%) and feces (15%). The elimination half-life is approximately 12 hours in patients with rheumatoid arthritis (RA).[63229]

Affected cytochrome P450 (CYP450) isoenzymes and drug transporters: CYP3A4, OAT3, P-glycoprotein (P-gp), BCRP, and MATE2-K

In vitro studies indicate that baricitinib is a substrate of CYP3A4, OAT3, P-gp, BCRP, and MATE2-K. In clinical pharmacology studies, coadministration with ketoconazole (a strong CYP3A4) did not have an effect on the pharmacokinetics of baricitinib. In addition, no clinically meaningful effects on baricitinib pharmacokinetics when it was coadministered with fluconazole (CYP3A/CYP2C19/CYP2C9 inhibitor) or rifampin (a strong CYP3A4 inducer). Coadministration with probenecid (a strong OAT3 inhibitor) resulted in an approximately 2-fold increase in baricitinib exposure. Coadministration with OAT3 inhibitors with less inhibition potential (i.e., ibuprofen and diclofenac) had minimal effect on baricitinib exposure. No clinically meaningful effect on the

pharmacokinetics of baricitinib was noted with the coadministration of cyclosporine (a P-gp and BCRP inhibitor). In vitro data indicate baricitinib inhibits OAT1, OAT2, OAT3, OCT1, OCT2, OAT1B3, BCRP, and MATE1 and MATE2-K, but clinically meaningful changes in the pharmacokinetics of drugs that are substrates for these transporters are unlikely.[63229]

Route-Specific Pharmacokinetics

- **Oral Route**

  The absolute oral bioavailability of baricitinib is approximately 80%. In clinical trials, baricitinib was administered without regard to meals. Administration with meals is not associated with a clinically relevant effect on exposure. Peak plasma concentrations of baricitinib after oral administration were reached within 1 hour, and a dose-proportional increase in systemic exposure was observed in the therapeutic dose range. Steady-state concentrations are achieved in 2 to 3 days with negligible accumulation.[63229]

Special Populations

- **Hepatic Impairment**

  The systemic exposure and maximum concentration of baricitinib is increased by 1.19- and 1.08-fold for patients with moderate hepatic impairment compared to those with normal hepatic function; however, no dosage adjustment is recommended for mild or moderate hepatic impairment. Baricitinib is not recommended in patients with severe hepatic impairment due to a lack of data.[63229]

- **Renal Impairment**

  The systemic exposure (AUC) of baricitinib was increased by 1.41-, 2.22-, 4.05-, and 2.41-fold for mild, moderate, severe, and end-stage renal disease (ESRD with hemodialysis) renal impairment groups compared to subjects with normal renal function. The maximum concentration (Cmax) increased by 1.16-, 1.46-, 1.40- and 0.88-fold for mild, moderate, severe, and ESRD patients, respectively, compared to patients with normal renal function. Dosage reduction is recommended for patients with moderate renal impairment (estimated GFR of 30 to 60 mL/minute/1.73 m^2). Baricitinib is not recommended for use in patients with severe renal impairment (estimated GFR of less than 30 mL/minute/1.73 m^2).[63229]

- **Pediatrics**

  There are no pediatric data regarding the pharmacokinetics of baricitinib.[63229]

- **Geriatric**

  Age did not have a clinically relevant effect on the pharmacokinetic profile of baricitinib.[63229]

- **Gender Differences**

  Gender did not have a clinically relevant effect on the pharmacokinetic profile of baricitinib.[63229]

- **Ethnic Differences**

  Ethnic differences did not have a clinically relevant effect on the pharmacokinetic profile of baricitinib.[63229]

- **Obesity**

  Body weight did not have a clinically relevant effect on the pharmacokinetic profile of baricitinib. [63229]

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References

63229 – Olumiant (baricitinib) tablets package insert. Indianapolis, IN: Lilly USA, LLC; 2019 Oct.

Pregnancy/Breast-feeding

Pregnancy

Sufficient data are not available to inform a drug-associated risk for major birth defects or miscarriage with the use of baricitinib during human pregnancy. In embryofetal animal studies, oral administration to rats and rabbits at exposures greater than 20 and 84 times the maximum recommended human dose (MRHD), respectively, resulted in reduced fetal body weights, increased embryolethality (rabbits only), and dose-related increases in skeletal malformations. Developmental toxicity was not observed in pregnant rats and rabbits treated with baricitinib at approximately 5 and 13 times the MRHD, respectively. In a pre- and post-development study in pregnant rats, oral baricitinib administration at exposures approximately 43 times the MRHD resulted in a reduction in pup viability, decreased fetal birth weight, reduced fetal body weight gain, decreased cytotoxic T cells on post-natal day 35 with no evidence of recovery by day 65, and developmental delays that might be attributable to decreased body weight gain. No developmental toxicity was observed at exposures approximately 9 times the MRHD.[63229]

Breast-Feeding

Because of the potential for serious adverse reactions in a nursing infant, breast-feeding during baricitinib therapy is not recommended. No data are available on the presence of baricitinib in human milk, the effects of the drug on the breast-fed infant, or the effects on milk production. Baricitinib is present in the milk of lactating rats; the clinical relevance of this to human lactation is not known.[63229] Etanercept and infliximab may be potential alternatives to consider during breast-feeding. However, assessment of indication and patient-specific factors should be performed before considering an alternative agent.[61808] [62180]

Revision Date: 04/09/2020 06:44:46 PM

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63229 – Olumiant (baricitinib) tablets package insert. Indianapolis, IN: Lilly USA, LLC; 2019 Oct.

Interactions

Level 2 (Major)

- Abatacept
- Adalimumab
- Anakinra
- Azathioprine
- Bacillus Calmette-Guerin Vaccine, BCG
- Canakinumab
- Certolizumab pegol
- Colchicine; Probenecid
- Cyclosporine
- Etanercept
- Golimumab
- Infliximab
- Influenza Virus Vaccine
- Intranasal Influenza Vaccine
- Live Vaccines
- Measles Virus; Mumps Virus; Rubella Virus; Varicella Virus Vaccine, Live
- Measles/Mumps/Rubella Vaccines, MMR
- Probenecid
- Rituximab
- Rituximab; Hyaluronidase
- Rotavirus Vaccine
- Rubella Virus Vaccine Live
- Sarilumab
- Secukinumab
- Smallpox and Monkeypox Vaccine, Live, Nonreplicating
- Smallpox Vaccine, Vaccinia Vaccine
- Tocilizumab
- Tofacitinib
- Tumor Necrosis Factor modifiers
- Typhoid Vaccine
- Upadacitinib
- Ustekinumab
- Varicella-Zoster Virus Vaccine, Live
- Yellow Fever Vaccine, Live

Level 3 (Moderate)

- Leflunomide
- Teriflunomide

Abatacept: (Major) Concomitant use of baricitinib with biologic DMARDs, such as abatacept, is not recommended because of the possibility of additive immunosuppression and increased infection risk. There is insufficient experience to assess the safety and efficacy of this combination. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [31761] [63229]

Adalimumab: (Major) Concomitant use of baricitinib with biologic DMARDs, such as tumor necrosis factor (TNF) modifiers, is not recommended because of the possibility of additive immunosuppression and increased infection risk. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Anakinra: (Major) Concomitant use of baricitinib with biologic DMARDs, such as anakinra, is not recommended because of the possibility of increased immunosuppression and increased infection risk. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Azathioprine: (Major) Concomitant use of baricitinib with azathioprine is not recommended because of the possibility of additive immunosuppression and increased infection risk. There is insufficient experience to assess

the safety and efficacy of this combination. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Bacillus Calmette-Guerin Vaccine, BCG: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

Canakinumab: (Major) Concomitant use of baricitinib with biologic DMARDs, such as canakinumab, is not recommended because of the possibility of additive immunosuppression and increased infection risk. [63229]

Certolizumab pegol: (Major) Concomitant use of baricitinib with biologic DMARDs, such as tumor necrosis factor (TNF) modifiers, is not recommended because of the possibility of additive immunosuppression and increased infection risk. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Colchicine; Probenecid: (Major) Reduce the dose of baricitinib to 1 mg/day PO in patients receiving concomitant therapy with probenecid. Coadministration of baricitinib and probenecid may result in increased baricitinib exposure. Baricitinib is an OAT3 substrate and probenecid is a strong OAT3 inhibitor. In a drug interaction study, administration of probenecid increased baricitinib exposure by 2-fold. [63229]

Cyclosporine: (Major) Concomitant use of baricitinib with cyclosporine is not recommended because of the possibility of additive immunosuppression and increased infection risk. There is insufficient experience to assess the safety and efficacy of this combination. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Etanercept: (Major) Concomitant use of baricitinib with biologic DMARDs, such as tumor necrosis factor (TNF) modifiers, is not recommended because of the possibility of additive immunosuppression and increased infection risk. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Golimumab: (Major) Concomitant use of baricitinib with biologic DMARDs, such as tumor necrosis factor (TNF) modifiers, is not recommended because of the possibility of additive immunosuppression and increased infection risk. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Infliximab: (Major) Concomitant use of baricitinib with biologic DMARDs, such as tumor necrosis factor (TNF) modifiers, is not recommended because of the possibility of additive immunosuppression and increased infection risk. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Influenza Virus Vaccine: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

Intranasal Influenza Vaccine: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

Leflunomide: (Moderate) Monitor for increased baricitinib effects if administered with leflunomide as baricitinib exposure may increase; a baricitinib dose reduction may be necessary. Baricitinib is an OAT3 substrate; leflunomide is an OAT3 inhibitor. [49634] [63229]

Live Vaccines: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

Measles Virus; Mumps Virus; Rubella Virus; Varicella Virus Vaccine, Live: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

Measles/Mumps/Rubella Vaccines, MMR: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

Probenecid: (Major) Reduce the dose of baricitinib to 1 mg/day PO in patients receiving concomitant therapy with probenecid. Coadministration of baricitinib and probenecid may result in increased baricitinib exposure. Baricitinib is an OAT3 substrate and probenecid is a strong OAT3 inhibitor. In a drug interaction study, administration of probenecid increased baricitinib exposure by 2-fold. [63229]

Rituximab: (Major) Concomitant use of baricitinib with biologic DMARDs, such as rituximab, is not recommended because of the possibility of additive immunosuppression and increased infection risk. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Rituximab; Hyaluronidase: (Major) Concomitant use of baricitinib with biologic DMARDs, such as rituximab, is not recommended because of the possibility of additive immunosuppression and increased infection risk. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Rotavirus Vaccine: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

Rubella Virus Vaccine Live: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

Sarilumab: (Major) Avoid the concomitant use of sarilumab with other biological DMARDs such as baricitinib; coadministration has not been studied and may result in additive immunosuppression and increased risk of infection. [61976] [63229]

Secukinumab: (Major) Concomitant use of baricitinib with biologic DMARDs, such as secukinumab, is not recommended because of the possibility of additive immunosuppression and increased infection risk. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Smallpox and Monkeypox Vaccine, Live, Nonreplicating: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

Smallpox Vaccine, Vaccinia Vaccine: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

Teriflunomide: (Moderate) Monitor for increased baricitinib effects if administered with teriflunomide as baricitinib exposure may increase; a baricitinib dose reduction may be necessary. Baricitinib is an OAT3 substrate; teriflunomide is an OAT3 inhibitor. [51794] [63229]

Tocilizumab: (Major) Avoid the concomitant use of tocilizumab with other biological DMARDs such as baricitinib; coadministration has not been studied and may result in additive immunosuppression and increased risk of infection. [38283] [63229]

Tofacitinib: (Major) Concomitant use of baricitinib with tofacitinib is not recommended because of the duplication of the mechanism of action (both are Janus kinase inhibitors, also known as JAK inhibitors) and the possibility of increased immunosuppression and increased infection risk. Both drugs are known to cause elevations in hepatic enzymes and gastrointestinal perforation, and a possibility for increased thrombotic risk. [63229]

Tumor Necrosis Factor modifiers: (Major) Concomitant use of baricitinib with biologic DMARDs, such as tumor necrosis factor (TNF) modifiers, is not recommended because of the possibility of additive immunosuppression and increased infection risk. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Typhoid Vaccine: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

Upadacitinib: (Major) Concomitant use of baricitinib with upadacitinib is not recommended because of the duplication of the mechanism of action (both are Janus kinase inhibitors, also known as JAK inhibitors) and the possibility of increased immunosuppression and increased infection risk. Both drugs are known to cause elevations in hepatic enzymes and gastrointestinal perforation, and a possibility for increased thrombotic risk. [64572]

Ustekinumab: (Major) Concomitant use of baricitinib with biologic DMARDs, such as ustekinumab, is not recommended because of the possibility of additive immunosuppression and increased infection risk. Baricitinib may be used as monotherapy or concomitantly with methotrexate or other nonbiologic DMARDs. [63229]

Varicella-Zoster Virus Vaccine, Live: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

Yellow Fever Vaccine, Live: (Major) Do not administer live virus vaccines to patients taking baricitinib, as no data are available on the secondary transmission of infection by live vaccines. Also, no data are available on the response to vaccination with any vaccine during baricitinib receipt. Before baricitinib initiation, review the

vaccination status of patients, and update immunizations in agreement with current immunization guidelines. [63229]

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51794 – Teriflunomide (Aubagio) tablets package insert. Genzyme Corporation: Cambridge, MA; 2020 Feb.

61976 – Kevzara (sarilumab) package insert. Bridgewater, NJ: Sanofi-Aventis US. LLC; 2018 Apr.

63229 – Olumiant (baricitinib) tablets package insert. Indianapolis, IN: Lilly USA, LLC; 2019 Oct.

64572 – Rinvoq (upadacitinib) package insert. North Chicago, IL: Abbvie Inc.; 2019 Aug.

Monitoring Parameters

- CBC with differential
- hemoglobin/hematocrit
- LFTs
- serum cholesterol profile
- serum creatinine/BUN
- skin cancer screening exam
- tuberculin skin test

US Drug Names

- OLUMIANT

Global Drug names

Austria

- Olumiant - (Lilly)

Belgium

- Olumiant - (Lilly)

Canada

- Olumiant - (Lilly)

Denmark

- Olumiant - (Lilly)

Finland

- Olumiant - (Lilly)

Germany

- Olumiant - (Lilly)

Ireland

- Olumiant - (Lilly)

Israel

- Olumiant - (Lilly)

Japan

- Olumiant - (Lilly)

Netherlands

- Olumiant - (Lilly)

Norway

- Olumiant - (Lilly)

Poland

- Olumiant - (Lilly)

Spain

- Olumiant - (Lilly)

Sweden

- Olumiant - (Lilly)

Switzerland

- Olumiant - (Lilly)

United Kingdom

- Olumiant - (Lilly)
