Intyma® Baricitinib

Description

Intyma® contains Baricitinib as an active substance.

Dosage Form & Strengths

2 mg and 4 mg film-coated tablets

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.

Indications

Baricitinib is indicated for the following conditions:

- **Moderate to severe active Rheumatoid Arthritis** (with an inadequate response to one or more Tumor Necrosis Factor (TNF) antagonist therapies)
- **Severe Alopecia Areata**
- **Atopic Dermatitis** (off-label use, **EMA approved**)
- **Systemic Lupus Erythematosus** (off-label use)
- **COVID-19, Hospitalized patients** (in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.)

Limitation of use: Use of baricitinib in combination with other JAK inhibitors, biologic DMARDs, biologic immunomodulators, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Dosing

- Rheumatoid Arthritis:
  2 mg once daily
  - 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 DMARD naïve patients with moderate to high disease activity.

- Alopecia Areata:
  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.

- Atopic Dermatitis:
  4 mg once daily is recommended.

- Systemic Lupus Erythematosus:
  4 mg once daily is recommended.

- COVID-19, Hospitalized patients:
  4 mg once daily, as part of an appropriate combination regimen, for 14 days or until hospital discharge, whichever is first.

Dosing in Hepatic and Renal Impairment

- **Hepatic impairment prior to treatment initiation:**
  - **Mild to moderate impairment:** No dosage adjustment necessary.
  - **Severe impairment:** Use is not recommended (has not been studied).

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

- **Renal Impairment:**
  - **eGFR ≥ 60 mL/minute/1.73 m^2:** No dosage adjustment necessary.
  - **eGFR 30 to 60 mL/minute/1.73 m^2:** Reduce dose to 1 mg once daily (if taking 2 mg daily) or 2 mg once daily (if taking 4 mg daily).
  - **eGFR <30 mL/minute/1.73 m^2:** Use is not recommended.
  - **Hemodialysis:** Use is not recommended.

Adverse Reactions (In patients with an anticipated long-term duration of therapy)

>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%)

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.
- Consider **discontinuing use 1 month prior to conception.**

Pregnancy Considerations

- Outcome data following baricitinib exposure in pregnancy are limited.
- Recommendations for use of baricitinib in pregnant patients with rheumatic and musculoskeletal diseases are not available due to lack of data.
- Placental transfer may be expected based on molecular weight.

Breastfeeding Considerations

- It is not known if baricitinib is present in breast milk (transfer into breast milk may be expected based on molecular weight).
- Recommendations for use of baricitinib in breastfeeding patients with rheumatic and musculoskeletal diseases are not available due to lack of data.
- 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.**

Contraindications

Hypersensitivity to baricitinib or any component of the formulation.

Warnings/ Precautions

GI perforations (Use with caution in patients at increased risk for GI perforation (e.g., history of diverticulitis)); Hematologic toxicity (Do not initiate therapy in patients with an anticipated long-term duration of therapy with an absolute lymphocyte count <500 cells/mm^3, ANC <1,000 cells/mm^3, or Hb <8 g/dL.); Hepatic effects; Hypersensitivity; Infections including Tuberculosis; Lipid abnormalities; Malignancy.

Monitoring Parameters

In all patients:

- Lymphocyte, neutrophil, platelet counts, & Hb (baseline and periodically thereafter)
- 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:

- 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).

Storage and Handling

- Store Intyma® below 30°C and in the original package in order to protect from light and moisture.
- Do not use this medicine after the expiry date which is stated on the blister and carton after 'EXP'. The expiry date refers to the last day of that month.
- Do not discard any medicines via wastewater or household waste.
- Keep this medicine out of the sight and reach of children.

Reference:

Baricitinib Drug Information, UpToDate Database, Accessed in 2022.

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