Upajak

Upadacitinib INN

Everest

COMPOSITION

UPAJAK tablet: Each extended-release film coated tablet contains Upadacitinib INN 15 mg.

PHARMACOLOGY

Upadacitinib is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression. Upadacitinib modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs.

INDICATION

Upajak is a Janus kinase (JAK) inhibitor indicated for

• The treatment of adults with moderate to severe active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers.

• The treatment of adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.

• The treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.

• The treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.

• The treatment of adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers.

• The treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.

• The treatment of adults with active nonradiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.

• The treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.

Limitation of Use

Not recommended for use in combination with other JAK inhibitors, biological immunemodulators, or with other potent immunosuppressants.

Preliminary tests prior prescribing Upadacitinib

Active and latent tuberculosis (TB) infection evaluation-If positive, treat for TB prior to Upadacitinib use.

• Viral hepatitis screening in accordance with clinical guidelines - Upadacitinib initiation is not recommended in patients with active hepatitis B or hepatitis C).

• A complete blood count - Upadacitinib initiation is not recommended in patients with an absolute lymphocyte count less than 500 cells/mm3, absolute neutrophil count less than 1000 cells/mm3, or hemoglobin level less than 8 g/dL.

• Baseline hepatic function: Upadacitinib initiation is not recommended for patients with severe hepatic impairment (Child-Pugh C).

• Pregnancy Status: Verify the pregnancy status of females of reproductive potential prior to starting treatment.

DOSAGE AND ADMINISTRATION

Rheumatoid Arthritis: 15 mg once daily.

Psoriatic Arthritis (Adults 18 Years of Age and Older): 15 mg once daily.

Atopic Dermatitis

Age 12 kg – 65 kg (Weighing at least 40 kg): Initiate with 15 mg once daily. If an adequate response is not achieved, consider increasing the dosage to 30 mg once daily. Discontinue if an adequate response is not achieved with the 30 mg dose.

Adults 65 Years of Age and Older: 15 mg onc e daily.

Ulcerative Colitis (Adult Patients): Induction: 45 mg once daily for 8 weeks.

Maintenance: 15 mg once daily. A dosage of 30 mg once daily may be considered for patients with refractory, severe or extensive disease. Discontinue if an adequate therapeutic response is not achieved with the 30 mg dosage.

Crohn's Disease (Adult Patients)

Induction: 45 mg once daily for 12 weeks.

Maintenance: 15 mg once daily. A dosage of 30 mg once daily may be considered for patients with refractory, severe or extensive disease. Discontinue if an adequate therapeutic response is not achieved with the 30 mg dosage.

Ankylosing Spondylitis: 15 mg once daily.

Non-radiographic Axial Spondyloarthritis: 15 mg once daily.

Polyarticular Juvenile Idiopathic Arthritis: (30 kg and greater): 15 mg once daily.

CONTRAINDICATION

Known hypersensitivity to upadacitinib or any of the excipients in upadacitinib.

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WARNINGS AND PRECAUTION

Serious Infections: Avoid use in patients with active, serious infection, including localized infections.

Hypersensitivity: Serious hypersensitivity reactions (e.g., anaphylaxis) have been reported. Discontinue if a serious hypersensitivity reaction occurs.

Gastrointestinal (GI) Perforations: Monitor patients at risk for GI perforations and promptly evaluate patients with symptoms.

Laboratory Abnormalities: Monitoring recommended due to potential changes in lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids.

Embryo-Fetal Toxicity: May cause fetal harm based on animal studies. Advise female patients of reproductive potential of the potential risk to a fetus and to use effective contraception.

Vaccinations: Avoid use with live vaccines.

Medication Residue in Stool: Observed in stool or ostomy output in patients with shortened GI transit times. Monitor patients clinically and consider alternative treatment if inadequate therapeutic response.

SIDE EFFECTS

Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and nonradiographic axial spondyloarthritis: Adverse reactions (≥ 1%) were: upper respiratory tract infections, herpes zoster, herpes simplex, bronchitis, nausea, cough, pyrexia, acne, and headache.

Atopic Dermatitis: Adverse reactions (≥ 1%) are: upper respiratory tract infections, acne, herpes simplex, headache, blood creatine phosphokinase increased, cough, hypersensitivity, folliculitis, nausea, abdominal pain, pyrexia, increased weight, herpes zoster, influenza, fatigue, neutropenia, myalgia, and influenza like illness.

Ulcerative Colitis: Adverse reactions (≥ 5%) reported during induction or maintenance are: upper respiratory tract infections, increased blood creatine phosphokinase, acne, neutropenia, elevated liver enzymes, and rash.

Crohn's Disease: Adverse reactions (≥ 5%) reported during induction or maintenance are: upper respiratory tract infections, anemia, pyrexia, acne, herpes zoster, and headache.

USE IN SPECIFIC POPULATIONS

Pregnancy: Animal studies show potential risks to developing fetuses, including skeletal and cardiovascular malformations, increased post-implantation loss, and decreased fetal body weights at various doses. Human data is limited, and all pregnancies carry inherent risks. Increased disease activity in conditions like rheumatoid arthritis or inflammatory bowel disease may lead to adverse pregnancy outcomes.

Lactation: Advise not to breastfeed.

Pediatric Use: No data available for pediatric patients under 2 years.

Hepatic Impairment: Upadacitinib is not recommended in patients with severe hepatic impairment.

Renal Impairment: For Upadacitinib, no dosage adjustment is needed for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, or polyarticular juvenile idiopathic arthritis patients with mild to severe renal impairment. For atopic dermatitis, the maximum dose is 15 mg once daily with severe renal impairment. For ulcerative colitis or Crohn's disease with severe renal impairment, the recommended dose is 30 mg once daily for induction and 15 mg once daily for maintenance. Upadacitinib is not recommended in end-stage renal disease for atopic dermatitis, ulcerative colitis, or Crohn's disease.

OVERDOSE

In case of an overdose, it is recommended that the patient be monitored for signs and symptoms of adverse reactions. Patients who develop adverse reactions should receive appropriate treatment.

DRUG INTERACTIONS

Upadacitinib exposure is increased when co-administered with strong CYP3A4 inhibitors (such as ketoconazole). Upadacitinib should be used with caution in patients receiving chronic treatment with strong CYP3A4 inhibitors. Upadacitinib exposure is decreased when co-administered with strong CYP3A4 inducers (such as rifampin), which may lead to reduced therapeutic effect of Upadacitinib. Coadministration of Upadacitinib with strong CYP3A4 inducers is not recommended.

PHARMACEUTICAL INFORMATION

Storage Condition

Store below 30°C, in a cool and dry place. Keep away from light and keep out of the reach of children.

HOW SUPPLIED

UPAJAK tablet: Each HDPE container contains 30 tablets (Each tablet contains 15 mg of Upadacitinib), a silica gel desiccant and polyester coil with child resistant closure.

Manufactured by
Everest Pharmaceuticals Ltd.
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