Dacivo™

Upadacitinib Hemihydrate INN

Jenphar Bangladesh | جنفار بنغلاديش

Composition:

Dacivo™ 15 mg Tablet: Each extended-release tablet contains Upadacitinib Hemihydrate INN equivalent to Upadacitinib 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.

Indications:

Upadacitinib is a Janus kinase (JAK) inhibitor indicated for the treatment of:

Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers.

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

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. (1.2)

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

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.

Limitations of Use: Upadacitinib is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.

Limitations of Use: Upadacitinib is not recommended for use in combination with other JAK inhibitors, biological therapies for ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine.

Adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers.

Limitations of Use: Upadacitinib is not recommended for use in combination with other JAK inhibitors, biological therapies for Crohn's disease, or with potent immunosuppressants such as azathioprine and cyclosporine.

Adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.

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

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

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

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.

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

Dosage and Administration:

Rheumatoid Arthritis, Ankylosing Spondylitis, and Non-radiographic Axial Spondyloarthritis

Adults: The recommended dosage of Upadacitinib is 15 mg once daily.

Psoriatic Arthritis

Pediatric Patients 2 to less than 18 Years of Age Weighing at Least 10 kg: The recommended dosage is based on body weight.

Adults: The recommended dosage of Upadacitinib is 15 mg once daily.

Atopic Dermatitis

Pediatric Patients 12 Years of Age and Older Weighing at Least 40 kg and Adults Less Than 65 Years of Age: Initiate treatment with Upadacitinib 15 mg orally once daily. If an adequate response is not achieved, consider increasing the dosage to 30 mg orally once daily.

Adults 65 Years of Age and Older: Recommended dosage of Upadacitinib is 15 mg once daily.

Severe Renal Impairment: Recommended dosage of Upadacitinib is 15 mg once daily.

Ulcerative Colitis

Adults: The recommended induction dosage of Upadacitinib is 45 mg once daily for 8 weeks. The recommended maintenance dosage of Upadacitinib is 15 mg once daily. A maintenance dosage of 30 mg once daily may be considered for patients with refractory, severe, or extensive disease. Discontinue Upadacitinib if adequate therapeutic response is not achieved with the 30 mg dosage. Use the lowest effective dosage needed to maintain response.

Crohn's Disease

Adults: The recommended induction dosage of Upadacitinib is 45 mg once daily for 12 weeks. The recommended maintenance dosage of Upadacitinib is 15 mg once daily. A maintenance dosage of 30 mg once daily may be considered for patients with refractory, severe, or extensive disease. Discontinue Upadacitinib if an adequate therapeutic response is not achieved with the 30 mg dosage. Use the lowest effective dosage needed to maintain response.

Polyarticular Juvenile Idiopathic Arthritis

The recommended dosage is based on body weight.

Contraindications:

Known hypersensitivity to Upadacitinib or any of the excipients.

Adverse Reaction:

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.

Warning and Precautions:

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.

Use in Specific Populations:

Lactation: Advise not to breastfeed.

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

Drug Interaction:

Strong CYP3A4 Inhibitors: Upadacitinib exposure is increased when it is co-administered with a strong CYP3A4 inhibitor (such as ketoconazole, clarithromycin, and grapefruit), which may increase the risk of adverse reactions.

For patients with atopic dermatitis, coadministration of Upadacitinib 30 mg once daily with strong CYP3A4 inhibitors is not recommended. For patients with ulcerative colitis or Crohn's disease taking strong CYP3A4 inhibitors, reduce the Upadacitinib induction dosage to 30 mg once daily. The recommended maintenance dosage is 15 mg once daily.

Strong CYP3A4 Inducers: Coadministration of Upadacitinib with strong CYP3A4 inducers is not recommended.

Overdose:

In case of an overdose, it is recommended that the patient be monitored for signs and symptoms of adverse reactions.

Storage Condition:

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

Packaging:

Dacivo™ 15 mg Tablet: Each box contains 10 tablets and one packet silica gel in a sealed HDPE container.

Manufactured by:

Jenphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.

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