

Tofatake 5 Tablet

Tofacitinib (5mg) Tablet

Category: Janus Kinase (JAK) Inhibitor

Dosage Form: Oral Tablet

Description:

Tofacitinib is an oral Janus Kinase (JAK) inhibitor used to treat moderate to severe rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis. By inhibiting Janus kinases (enzymes involved in the immune response), Tofacitinib works by modulating the body's immune system, reducing inflammation, and preventing tissue damage. It is effective in controlling symptoms of autoimmune conditions and helping to improve overall quality of life for patients with these conditions.

Composition:

- **Active Ingredient:**
 - Tofacitinib – 5mg per tablet
 - **Excipients:**
 - Includes binders, stabilizers, and fillers as per formulation (e.g., microcrystalline cellulose, lactose monohydrate, etc.)
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Indications:

- **Rheumatoid Arthritis (RA):** Treatment of moderate to severe active rheumatoid arthritis in adults who have had an inadequate response to methotrexate or

other DMARDs (disease-modifying antirheumatic drugs).

- **Psoriatic Arthritis (PsA):** Management of active psoriatic arthritis in adults who have had an inadequate response to conventional therapy.
- **Ulcerative Colitis (UC):** Treatment of moderate to severe ulcerative colitis in adults who have had an inadequate response to conventional therapies or biologics.

It is also used off-label in certain other autoimmune disorders as per medical discretion.

Dosage and Administration:

- **For Rheumatoid Arthritis:**
 - The usual dose is 5mg twice daily.
 - In certain cases, dose adjustments may be made based on the patient's response and tolerability.
- **For Psoriatic Arthritis and Ulcerative Colitis:**
 - Initial dose is typically 10mg twice daily for the first 8 weeks, followed by 5mg twice daily for maintenance.
- **Renal Impairment:** In patients with moderate renal impairment, the dose may need to be adjusted. For those with severe renal impairment, use should be avoided unless recommended by a physician.
- **Instructions for Use:**
 - Take the tablet orally with or without food.
 - Swallow the tablet whole. Do not crush, chew, or split the tablet.

- **Take the medication regularly at the same time each day to maximize benefits.**
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Mechanism of Action:

Tofacitinib works by inhibiting Janus kinases (JAKs), which are enzymes involved in the signaling pathways that mediate the immune system's inflammatory response. By blocking JAK1 and JAK3, Tofacitinib disrupts the activation of the immune cells responsible for causing inflammation and damage in conditions like rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis.

This leads to a reduction in immune system overactivity, helping to decrease symptoms such as pain, swelling, and damage to joints, as well as improve bowel function in ulcerative colitis.

Contraindications:

- **Hypersensitivity to Tofacitinib or any component of the formulation.**
 - **Active infections, including tuberculosis or opportunistic infections.**
 - **Severe liver impairment (use with caution and only under medical supervision).**
 - **Pregnancy and Lactation: Not recommended during pregnancy unless the benefit outweighs the risk. It is not known whether Tofacitinib is excreted in breast milk, so use during breastfeeding should be avoided unless absolutely necessary.**
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Warnings and Precautions:

- 1. Infections: Tofacitinib suppresses the immune system, which can increase the risk of serious infections, including tuberculosis, bacterial, fungal, and viral infections. Patients should be screened for infections before starting treatment and monitored during therapy.**
 - 2. Cancer Risk: Long-term use of JAK inhibitors may increase the risk of certain cancers, including lymphoma and other malignancies.**
 - 3. Blood Clot Risk: Tofacitinib may increase the risk of blood clots, especially in patients with cardiovascular disease or those at high risk for thromboembolic events.**
 - 4. Liver Enzyme Elevations: Monitor liver function during treatment. Discontinue if significant liver abnormalities occur.**
 - 5. Bone Fractures: Long-term use may increase the risk of bone fractures, so it is important to assess bone health, particularly in postmenopausal women or patients with other risk factors for fractures.**
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Adverse Effects:

Common Side Effects:

- **Headache**
- **Upper respiratory tract infections (e.g., sinusitis)**
- **Diarrhea, nausea, and other gastrointestinal issues**
- **Elevated liver enzymes**
- **Rash**
- **Hypertension (high blood pressure)**

Serious Side Effects:

- **Serious infections (e.g., tuberculosis, pneumonia)**
- **Blood clots (deep vein thrombosis, pulmonary embolism)**

- **Cancer (including lymphoma, skin cancers)**
 - **Liver toxicity (hepatotoxicity)**
 - **Severe allergic reactions (e.g., swelling of the face, lips, or throat, difficulty breathing)**
 - **Bone fractures due to weakening of the bones over time.**
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Drug Interactions:

- **Immunosuppressive Drugs:** Avoid using with other immunosuppressive agents (e.g., biologics, other JAK inhibitors, methotrexate) unless under medical supervision.
 - **CYP3A4 Inhibitors/Inducers:** Tofacitinib is metabolized by the CYP3A4 enzyme, so drugs that inhibit or induce this enzyme (e.g., ketoconazole, rifampin) may affect Tofacitinib levels.
 - **Live Vaccines:** Use caution with live vaccines, as Tofacitinib may reduce the immune response to these vaccines.
 - **Statins:** Concomitant use with statins may increase the risk of muscle toxicity.
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Storage Instructions:

- **Store at room temperature (15°C - 30°C).**
 - **Keep in a tightly closed container and protect from moisture.**
 - **Keep out of reach of children.**
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Key Points:

- **Tofacitinib (5mg) is a Janus kinase (JAK) inhibitor used to treat moderate to severe rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis.**

- **It works by reducing inflammation and modulating the immune system to help control symptoms of these autoimmune diseases.**
- **Regular monitoring for infections, liver function, and lipid levels is necessary during treatment.**
- **Not recommended for use in active infections, severe liver disease, or during pregnancy without careful consideration of risks and benefits.**

Always consult a healthcare provider for personalized advice, dosage, and potential side effects.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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