Information For the Use Leflunomide (20mg)

Lefutyle 20 tablet

Leflunomide 20mg Tablets Information

Generic Name:

Leflunomide

Strength:

20mg

Form:

Tablet

Therapeutic Class:

Immunosuppressant, Disease-Modifying Antirheumatic Drug (DMARD)

Description

Leflunomide is a potent disease-modifying antirheumatic drug (DMARD) and immunosuppressant used to treat autoimmune conditions, primarily rheumatoid arthritis and psoriatic arthritis. It works by suppressing the activity of certain immune cells (particularly T-cells), which are responsible for inflammation and joint damage in autoimmune diseases. Leflunomide inhibits the enzyme dihydroorotate dehydrogenase involved in the synthesis of pyrimidines, crucial for the proliferation of immune cells. By blocking this process, Leflunomide reduces inflammation and helps prevent further damage to the joints.

In addition to its primary uses, Leflunomide is sometimes used off-label for other autoimmune disorders.

Indications

Leflunomide 20mg tablets are indicated for:

- Rheumatoid Arthritis: To reduce the signs and symptoms of moderate to severe rheumatoid arthritis and to slow the progression of joint damage.
- Psoriatic Arthritis: To reduce inflammation, pain, and swelling associated with psoriatic arthritis.
- Other Autoimmune Diseases: Occasionally used in other autoimmune conditions under the supervision of a healthcare provider.

Dosage and Administration

- Recommended Dose:
 - Initial Dose (Loading Dose): Typically, 100mg (5 tablets of 20mg) daily for 3 days to achieve quicker therapeutic effects.
 - Maintenance Dose: After the loading dose, reduce the dose to 20mg once daily.
 - Alternative Dosing: In some cases, a lower maintenance dose of 10mg daily may be recommended, based on individual tolerance and response.

Note: Always follow the exact dosing instructions provided by your healthcare provider for optimal results.

Contraindications

Leflunomide is contraindicated in the following situations:

- Pregnancy: Leflunomide can cause severe birth defects or fetal death. It is contraindicated in pregnant women and should not be used by women of childbearing age unless they are using reliable contraception.
- Severe Liver Disease: Not to be used in patients with severe liver impairment or active liver disease.
- Hypersensitivity: Known allergy or hypersensitivity to Leflunomide or any of the components of the tablet.
- Severe Immunosuppression: Not suitable for patients with severely compromised immune systems, including those with HIV/AIDS or ongoing infections.

Precautions

- Liver Function: Leflunomide can cause liver toxicity, so liver function tests should be performed before initiating treatment and regularly thereafter. If liver enzyme levels rise, the dose may need to be adjusted or discontinued.
- Pregnancy and Lactation: Leflunomide is contraindicated during pregnancy. Women who plan to become pregnant or are breastfeeding should discuss this with their healthcare provider. A

washout procedure may be necessary before pregnancy.

- Infection Risk: Leflunomide suppresses the immune system, increasing the risk of infections. Patients should be monitored for signs of infection, and the drug should be stopped if a serious infection develops.
- Bone Marrow Suppression: Leflunomide may cause bone marrow suppression, leading to a reduced count of red blood cells, white blood cells, or platelets. Routine blood monitoring is essential.
- Kidney Function: Use with caution in patients with kidney impairment.

Side Effects

Common side effects may include:

- Gastrointestinal: Nausea, diarrhea, or abdominal discomfort.
- Headache: Some patients may experience mild headaches.
- Rash: Skin rashes or itching may occur.
- Elevated Liver Enzymes: Liver enzyme levels may rise, which should be monitored with regular blood tests.
- Hair Thinning: Some patients may experience mild hair loss.

Serious side effects (rare but possible) include:

• Severe Liver Damage: Symptoms such as yellowing of the skin or eyes (jaundice), dark urine, and upper abdominal pain.

- Infections: Fever, chills, and other signs of infections may indicate a serious issue.
- Severe Bone Marrow Suppression: Symptoms may include unusual bruising or bleeding, pale skin, or extreme fatigue.
- Peripheral Neuropathy: Tingling, numbness, or pain in the hands or feet.

If any severe side effects occur, seek medical attention immediately.

Drug Interactions

- Immunosuppressants: Leflunomide may increase the effects of other immunosuppressive drugs (e.g., methotrexate, corticosteroids), increasing the risk of infections and side effects.
- Liver Enzyme Modifiers: Drugs that affect liver enzymes (e.g., rifampin) may alter Leflunomide's metabolism.
- Vaccines: Avoid live vaccines (e.g., MMR, varicella, BCG) during Leflunomide treatment as it may impair the immune response.
- Warfarin: Leflunomide may interact with blood thinners like warfarin, increasing the risk of bleeding.

Always inform your doctor about any other medications or supplements you are taking before starting Leflunomide.

Storage Instructions

• Store in a cool, dry place, away from direct sunlight (room temperature 15-30°C).

- Keep the bottle tightly closed when not in use.
- Keep out of reach of children and pets.
- Do not store in damp or humid conditions (e.g., bathroom).

Additional Notes

- Routine Monitoring: Regular blood tests are required to monitor liver function, blood cell counts, and overall health while taking Leflunomide.
- Washout Procedure: If discontinuing Leflunomide, a washout procedure may be required to clear the drug from the body. This is important for those planning pregnancy or discontinuing the drug for any reason.
- Long-Term Use: Leflunomide is often used for long-term treatment of autoimmune diseases. Continued use and regular check-ups with your healthcare provider are essential to monitor for side effects and ensure the drug is working effectively.

If you have any questions or concerns about Leflunomide 20mg tablets or its use, consult your healthcare provider for personalized guidance.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd. (An ISO 9001: 2015 Certified Co.) Plot no.: 367-FF, Industrial Area Phase-I, Panchkula-134113 TM: Trademark Applied for