Nodia®

Leflunomide tablet

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Presentation
Nodia® 10: Each film coated tablet contains Leflunomide USP 10 mg.

Description
Nodia is an isoxazole immunomodulatory agent which acts on the immune system, has been introduced recently as a disease-modifying antirheumatic drug. It inhibits dihydroorotate dehydrogenase (an enzyme involved in de novo pyrimidine synthesis) and has antiproliferative activity. Several *in vivo* and *in vitro* experimental models have demonstrated an anti-inflammatory effect.

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Indications and Uses
Nodia is indicated in adults for the treatment of active rheumatoid arthritis (RA) to reduce signs and symptoms and to retard structural damage as manifested by x-ray erosions and joint space narrowing .

Dosage and Administration
Nodia offers convenient once-daily oral dosing for RA patients. After a loading dose of 100 mg once daily for 3 days, the maintenance dose is 20 mg once daily. Leflunomide does not require stepwise dose increment over time. The dose may be decreased to 10 mg daily if tolerability issues arise.

Contraindications
Leflunomide is contraindicated in patients with known hypersensitivity to leflunomide or any of the other components of leflunomide, hepatic impairment, severe uncontrolled infections and bone marrow dysplasia.

Precautions
Caution should be taken for those female with child bearing potential who are not using reliable contraception and for the subject of renal insufficiency. Leflunomide should be stopped before becoming pregnant. Liver function should be monitored before starting treatment.

Side-effects
Adverse reactions associated with the use of leflunomide include diarrhea, nausea, vomiting, abdominal pain, headache, respiratory infection, bronchitis, elevated liver enzymes, aggravation of pre-existing hypertension, alopecia, and rash.

Use in pregnancy & lactation
Pregnancy : Leflunomide is not recommended for pregnant women. Pregnancy must be avoided during leflunomide treatment or prior to the completion of the drug elimination procedure after leflunomide treatment.

Nursing Mother : Leflunomide should not be used by nursing mothers. It is not known whether leflunomide is excreted in human milk. Many drugs are excreted in human milk and there is a potential for serious adverse reactions in nursing infants from leflunomide. Therefore, a decision should be made whether to proceed with nursing or initiate treatment with leflunomide, taking into account the importance of the drug to the mother.

Use in children
Not recommended for children below 18 years of age.

Drug interactions
Cholestyramine and activated charcoal help rapid elimination of leflunomide from body. Increased side effects may occur when leflunomide is given concomitantly with hepatotoxic substances.

Overdosage
There is no human experience regarding leflunomide overdosage. In the event of a significant overdose or toxicity, cholestyramine or charcoal administration is recommended to accelerate elimination.

Storage
Do not store above 30 ^{0}C. Keep away from light and out of reach of children.

Commercial Pack
Nodia® 10: Each box contains 10 blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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