

# Arthera™

Iguratimod tablet

## Presentation

Arthera™ : Each film coated tablet contains Iguratimod INN 25 mg.

## Description

Iguratimod is a synthetic small molecule classified as a disease-modifying anti-rheumatic drug (DMARD). It possesses anti-inflammatory, immunomodulatory, and bone metabolism-enhancing properties. It works by reducing the production of inflammatory cytokines and immunoglobulins, suppressing overactive immune responses, and promoting bone formation. These effects contribute to symptom relief and slowing of disease progression in patients with rheumatoid arthritis.

## Indication

Iguratimod is indicated for the treatment of active rheumatoid arthritis in adult patients. It is used to relieve joint pain and swelling, improve joint function and daily activities, and help achieve remission in those with moderate to severe disease activity.

## Dosage and Administration

Instruction	Details
General Adult Dose	1 tablet (25 mg) once daily after breakfast for more than 4 weeks.
Dose Adjustment	If instructed by your doctor, 1 tablet twice daily (after breakfast and supper); maximum 2 tablets (50 mg) daily.

If you miss a dose, simply skip it and take the next scheduled dose as usual. Do not take two doses at once to make up for a missed dose. If you accidentally take more than your prescribed dose, consult your doctor or pharmacist immediately. This medicine typically begins to show its effect within 16 weeks of starting treatment. Do not stop taking this medicine unless your doctor specifically instructs you to do so.

## Contraindications

Iguratimod should not be used in patients who are pregnant or breastfeeding, those who have a known allergy to Iguratimod, and individuals with active gastrointestinal ulcers, severe hepatic or renal dysfunction, or blood disorders such as low white blood cell count, low platelets, or anemia. It is also contraindicated in patients who are currently using other DMARDs or immunosuppressants without proper medical supervision.

## Precautions

Before and during treatment with Iguratimod, regular monitoring of liver function tests, blood counts, and renal function is essential. The drug should be used cautiously in patients with a history of heavy alcohol use, gastrointestinal conditions, or other chronic illnesses. Women of childbearing potential must have a negative pregnancy test before starting therapy and must use effective contraception throughout the treatment period and for at least one month after stopping the medication. Avoid alcohol and vaccinations during treatment unless advised by a healthcare provider.

## Side-effects

Very common side effects (more than 1 in 10 patients) include elevated liver enzymes.

Common side effects (more than 1 in 100 but less than 1 in 10) include nausea, anorexia, upper abdominal discomfort, rashes, headache, dizziness, fatigue, reduced white blood cell or platelet counts, insomnia, and abnormal ECG.

Rare side effects (less than 1 in 1000) may include vomiting, gastric or duodenal ulcers, reflux esophagitis, oral ulcers, facial swelling, fever, and flu-like symptoms.

Most side effects resolve upon dose reduction or drug discontinuation.

## Interactions

Caution should be exercised when Iguratimod is taken alongside other medications. Patients who are already receiving other disease-modifying anti-rheumatic drugs (DMARDs) such as Methotrexate, non-steroidal anti-inflammatory drugs (NSAIDs) like Ibuprofen or Diclofenac, or steroids and other immunosuppressive agents, should only use Iguratimod under strict medical supervision.

## Use in pregnancy and lactation

Iguratimod is not recommended during pregnancy as it may harm the developing fetus. Breastfeeding is also not advised during treatment with Iguratimod, as it is not known whether the drug is excreted in breast milk.

## Overdose

In case of an overdose, symptoms may include severe liver enzyme elevation, gastrointestinal irritation, and hematologic abnormalities. There is no specific antidote, so supportive care and symptomatic treatment should be provided. Emergency medical attention is strongly recommended.

## Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

## Commercial Packaging

Arthera™: Each box contains 2 blister strips of 10 tablets.