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The Bulletin from the Clinical Pharmacist

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Iguratimod

1. Drug class: Conventional synthetic disease-modifying anti-rheumatic drug (csDMARD); NF-κB inhibitor.

2. Mechanism of action: It mainly inhibits the NF-κB pathway, reducing production of TNF-α, IL-6 and pro-inflammatory cytokines and mediators. It also directly suppresses B-Cell terminal differentiation and Immunoglobulin/ autoantibody production, thereby dampening the autoimmune response in rheumatoid arthritis.

3. Indications

- Rheumatoid arthritis (RA): approved and widely used in Japan and China, often in combination with methotrexate as a csDMARD.
- Used in India for RA as an add-on or alternative csDMARD, following local rheumatology practice patterns; formal national guideline positioning may vary.

4. Dosing

Starting dose: 25 mg once daily for 4 weeks to assess tolerability

Maintenance dose: 25 mg twice daily (total 50 mg/day) orally, with or after food to reduce GI upset.

As combination therapy: commonly used with methotrexate as per RA csDMARD protocols, with standard MTX dosing unchanged.

5. Dose adjustment

Hepatic impairment: Avoid in active liver disease or elevated transaminases; discontinuation if ALT/AST >2–3× ULN

Renal impairment: no specific adjustment usually required in mild to moderate impairment, but use cautiously and monitor, as detailed PK data are limited

Elderly: start at lower end of dosing range and titrate carefully due to higher risk of hepatic and hematologic adverse effects

6. Contraindications

- Known hypersensitivity to Iguratimod or any component of the formulation.
- Severe hepatic impairment or significant active liver disease (due to risk of hepatotoxicity).
- History of severe hematologic disorders such as aplastic anemia or significant bone marrow failure.
- Pregnancy and lactation are generally considered contraindications/strongly discouraged because of insufficient safety data and potential risk; use only if no alternatives and potential benefit justifies risk

7. Adverse effects

Common (usually dose-related and often reversible): diarrhea, nausea, vomiting, abdominal pain, decreased appetite, stomatitis, rash, itching, urticaria, photosensitivity, nasopharyngitis and upper respiratory symptoms.

Laboratory and serious adverse effects: Elevated ALT/AST; potential drug-induced liver injury, Bone marrow suppression (aplastic anemia/cytopenias), Severe hypersensitivity or anaphylaxis.

8. Special populations

Pregnancy and lactation

- Not recommended; insufficient human data, and immunomodulatory mechanism suggests potential risk to fetus or infant.
- Discontinue or avoid in women who are pregnant or planning pregnancy; use effective contraception while on therapy and for a period after discontinuation as per local label.
- Breastfeeding is generally discouraged during treatment.