

**Composition :** Each Extended-Release Tablet contains Upadacitinib 15 mg as Upadacitinib Hemihydrate INN.

**Pharmacology :** Upadacitinib is a DMARD that works by inhibiting the Janus Kinases (JKSs) which are essential downstream cell signalling mediators of pro-inflammatory cytokines. It is believed that these pro-inflammatory cytokines play a role in many autoimmune inflammatory conditions, such as rheumatoid arthritis. In clinical trials, upadacitinib decreased the activity of pro-inflammatory interleukins, transiently increased the levels of lymphocytes and insignificantly decreased the levels of immunoglobulins from the baseline.

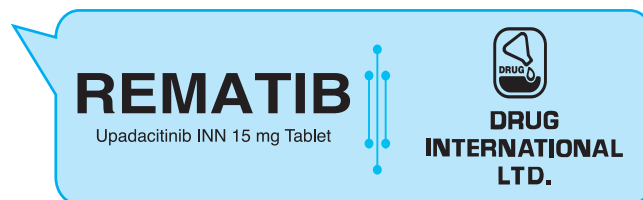
**Indication:** Rematib is a Janus Kinase (JAK) inhibitor indicated for the treatment of

- Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.
- Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.

**Dosage and administration:** Rematib should not be initiated if absolute lymphocyte count <500 cells/mm<sup>3</sup>, an absolute Neutrophil count (ANC) <1000 cells/mm<sup>3</sup>, or haemoglobin level <8 g/dl.

**Rheumatoid Arthritis & Psoriatic Arthritis:** The recommended dosage is 15 mg once daily.

**Atopic Dermatitis: Pediatric Patients 12 years of age and older weighing at least 40 kg and adults less than 65 years of age:** Initiate treatment with 15 mg orally once daily.



If an adequate response is not achieved, consider increasing the dosage to 30 mg orally once daily. *Adults 65 Years of Age and Older:* Recommended dosage is 15 mg once daily.

**Ulcerative Colitis: Adults:** The recommended induction dosage is 45 mg once daily for 8 weeks. The recommended maintenance dosage is 15 mg once daily. Or, as directed by the registered physician.

**Side Effects :** Adverse reactions (greater than or equal to 1%) are: Upper respiratory tract infections, nausea, cough, pyrexia, herpes zoster, abdominal pain and Acne.

**Use in pregnancy and lactation :** Pregnancy-There are no adequate and well-controlled studies in pregnant women. It should be avoided during pregnancy. Lactation-It is advised to avoid Upadacitinib during lactation.

**Use in child :** The safety and effectiveness of Upadacitinib in pediatric patients less than 18 years of age have not been established.

**Drug interactions:** Upadacitinib should be used with caution in patients receiving chronic treatment with strong CYP3A4 inhibitors (e.g., ketoconazole), Co-administration of Upadacitinib with strong CYP3A4 inducers (e.g., rifampin) is not recommended.

**Overdose :** In case of overdose, patients should seek immediate medical help. Patient should be managed by symptom and supportive care should be given.

**Storage :** Store at 30° c in a dry place.

**Packing:** Each box contains 1x10's tablets in blister pack.