

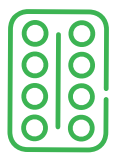
Rhofanib[®]

Tofacitinib



Description

Rhofanib[®] contains tofacitinib as an active substance.



Dosage Forms

The film-coated tablets are supplied in 5 mg and 10 mg strengths.



Indications

Tofacitinib is indicated for the treatment of:

- **Ankylosing spondylitis:** Treatment in adults who have had an inadequate response or intolerance to 1 or more tumor necrosis factor (TNF) blockers.
- **Polyarticular course juvenile idiopathic arthritis:** Treatment in pediatric patients ≥ 2 years of age who have had an inadequate response or intolerance to 1 or more TNF blockers.
- **Psoriatic arthritis:** Treatment in adults and pediatric patients ≥ 2 years of age who have had an inadequate response or intolerance to 1 or more TNF blockers.
- **Rheumatoid arthritis:** Treatment in adults who have had an inadequate response or intolerance to 1 or more TNF blockers.
- **Ulcerative colitis, moderate to severe, induction and maintenance of remission:** Treatment in adults who have had an inadequate response or intolerance to 1 or more TNF blockers.



Dosing: Adults

Ankylosing spondylitis, Psoriatic arthritis, Rheumatoid arthritis

- 5 mg twice daily.

Ulcerative colitis, moderate to severe, induction and maintenance of remission (alternative agent)

- Induction: 10 mg twice daily for at least 8 weeks.
- Maintenance: 5 mg twice daily.



Dosing: Pediatrics

Juvenile idiopathic arthritis, polyarticular course

- Children ≥ 2 years weighing ≥ 10 kg and Adolescents:
- 10 to < 20 kg: 3.2 mg twice daily.
- 20 to < 40 kg: 4 mg twice daily.
- ≥ 40 kg: 5 mg twice daily.



Administration

May be taken with or without food.



Adverse Reactions

>10%

- Endocrine & metabolic: Hyperlipidemia (including hypercholesterolemia [total: $\leq 9\%$], increased HDL cholesterol [10% to 12%], increased LDL cholesterol [15% to 19%], increased serum triglycerides [$\leq 9\%$])
- Infection (20% to 22%)
- Respiratory: Nasopharyngitis (3% to 14%)



Reproductive Considerations

Tofacitinib should generally be avoided or used cautiously before planned pregnancy, with other agents preferred and the drug discontinued one week before conception to minimize fetal exposure.



Pregnancy Considerations

Tofacitinib crosses the placenta and should generally be avoided in pregnancy, especially in the first trimester, because safety data are limited and alternative treatments are preferred.



Breastfeeding Considerations

Tofacitinib is present in breast milk, so breastfeeding is generally not recommended during treatment because of potential infant exposure and possible serious adverse effects.



Contraindications

Hypersensitivity to tofacitinib or any component of the formulation; severe hepatic impairment; pregnancy; breastfeeding.



Monitoring Parameters

- Lymphocyte count (baseline and every 3 months thereafter); neutrophil/platelet counts (baseline, after 4 to 8 weeks, and every 3 months thereafter); hemoglobin (baseline, after 4 to 8 weeks, and every 3 months thereafter)
- Lipids (4 to 8 weeks after therapy initiation and periodically)
- LFTs (baseline and periodically)
- Viral hepatitis (prior to initiating therapy in accordance with clinical guidelines)
- Tuberculosis (TB) infection and disease (latent and active TB) screening at baseline; signs/symptoms of infections (including TB) during and after therapy; abdominal symptoms
- Skin examinations (periodically, in patients at increased risk for skin cancer)
- Heart rate and blood pressure at baseline and periodically thereafter
- Measures of disease activity (e.g., ulcerative colitis: evidence of ongoing mucosal inflammation during direct examination [e.g., colonoscopy]; fecal calprotectin; serial C-reactive protein)



REFERENCE

Tofacitinib Drug Information, UpToDate [July 2026]