

Summary of prescribing information for MEROSYA tablets

Active Ingredient: Each film coated tablet of MEROSYA contains: Teriflunomide 7mg, 14 mg. **Indication:** for the treatment of patients with relapsing forms of multiple sclerosis. **Dosage:** 7 mg or 14 mg orally once daily, with or without food. **Contraindications:** Severe hepatic impairment. Pregnancy. Hypersensitivity. Current leflunomide treatment. **Warning and precautions:** Elimination of teriflunomide can be accelerated by administration of cholestyramine or activated charcoal for 11 days. Teriflunomide may decrease WBC. A recent CBC should be available before starting teriflunomide. Monitor for signs and symptoms of infection. Consider suspending treatment with teriflunomide in case of serious infection. Do not start teriflunomide in patients with active infections. Stop teriflunomide if patient has anaphylaxis, angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis; initiate rapid elimination. If patient develops symptoms consistent with peripheral neuropathy, evaluate patient and consider discontinuing teriflunomide. Teriflunomide may increase blood pressure. Measure blood pressure at treatment initiation and monitor blood pressure during treatment. **Pregnancy & Lactation:** Pregnancy: contraindicated. Lactation: Animal studies have shown excretion of teriflunomide in milk. Teriflunomide is contraindicated during breast-feeding. **Interaction:** Drugs metabolized by CYP2C8 and OAT3 transporters: Monitor patients because teriflunomide may increase exposure of these drugs. Teriflunomide may increase exposure of ethinylestradiol and levonorgestrel. Choose an appropriate oral contraceptive. Drugs metabolized by CYP1A2: Monitor patients because teriflunomide may decrease exposure of these drugs. Warfarin: Monitor INR as teriflunomide may decrease INR. Drugs metabolized by BCRP and OATP1B1/B3 transporters: Monitor patients because teriflunomide may increase exposure of these drugs. Rosuvastatin: The dose of rosuvastatin should not exceed 10 mg once daily in patients taking teriflunomide. **Adverse reactions:** common headache, diarrhea, nausea, alopecia, and increase in ALT. **Overdose:** There is no experience regarding teriflunomide overdose or intoxication in humans. Teriflunomide 70 mg daily up to 14 days was well tolerated by healthy subjects. In the event of clinically significant overdose or toxicity, cholestyramine or activated charcoal is recommended to accelerate elimination.

Prepared on 24th Feb 2020.

It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. productqueries@intaspharma.com