

MIGRON

MIRABEGRON INN

Compositions:

Migron 25 : Each film coated extended release tablet contains Mirabegron INN 25 mg.

Migron 50 : Each film coated extended release tablet contains Mirabegron INN 50 mg.

Pharmacology:

Mirabegron is a beta-3 adrenergic agonist. Mirabegron relaxes the detrusor smooth muscle during the storage phase of the urinary bladder by activation of beta-3 adrenergic receptor which increases bladder capacity.

Dosage And Administration:

The recommended starting dose of Mirabegron is 25 mg once daily, with or without food. Mirabegron 25 mg is effective within 8 weeks. Based on individual efficacy and tolerability, the dose may be increased to 50 mg once daily. Swallow whole with water, do not chew, divide or crush. Patients with Severe Renal Impairment or Patients with Moderate Hepatic Impairment: Maximum dose is 25 mg once daily. Patients with End Stage Renal Disease (ESRD) or Patients with Severe Hepatic Impairment: Not recommended.

Contraindications:

Mirabegron is contraindicated in patients with history of known hypersensitivity to mirabegron or any other components of it.

Warning And Precaution:

i. Increases in Blood Pressure: Mirabegron can increase blood pressure. Periodic blood pressure determinations are recommended, especially in hypertensive patients. Mirabegron is not recommended for use in severe uncontrolled hypertensive patients. ii. Urinary Retention in Patients With Bladder Outlet Obstruction and in Patients Taking Muscarinic Antagonist Drugs for Overactive Bladder: Administer with caution in these patients because of risk of urinary retention.

Side Effects:

Increased blood pressure, common cold symptoms, urinary tract infection and headache.

Use in Pregnancy and Lactation:

Pregnancy category C There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit to the patient outweighs the risk to the patient and fetus. Women who become pregnant during treatment are encouraged to contact their physician. Lactation It is not known whether mirabegron is excreted in human milk. Caution should be exercised when mirabegron is administered to a nursing woman.

Drug Interaction:

Mirabegron is CYP2D6 inhibitor and when used concomitantly with drugs metabolized by CYP2D6, especially narrow therapeutic index drugs, appropriate monitoring and possible dose adjustment of those drugs may be necessary.

Overdosage:

In case of overdose immediately consult with a registered physician.

Storage:

Store in a cool (between 15°C to 30°C) & dry place protected from light. Keep out of the reach of children.

Packing:

Migron 25 : Each box contains 2x10 tablets in Alu-Alu blister pack. Migron 50 : Each box contains 1x10 tablets in Alu-Alu blister pack.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.