

Mirabeg

Mirabegron Tablet

Presentation

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

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

Pharmacodynamic Properties

Mirabegron is an agonist of the human beta-3 adrenergic receptor (AR) as demonstrated by in vitro laboratory experiments using the cloned human beta-3 AR. Mirabegron relaxes the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle by activation of beta-3 AR which increases bladder capacity.

Pharmacokinetic Properties

C_{max} at approximately 3.5 hours. The absolute bioavailability increases from 29% at a dose of 25 mg to 35% at a dose of 50 mg. Steady state concentrations are achieved within 7 days of once daily dosing with mirabegron. After once daily administration, plasma exposure of mirabegron at steady state is approximately double that seen after a single dose.

Indications

Mirabegron is a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

Dosage and Administration

The recommended starting dose is 25 mg once daily, with or without food 25 mg is effective within 8 weeks. Based on individual efficacy and tolerability, may increase dose 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

None.

Side Effects

- Increased blood pressure
- Common cold symptoms (nasopharyngitis)
- Urinary tract infection
- Headache

Precautions

- **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.
- **Urinary Retention in Patients With Bladder Outlet Obstruction and in Patients Taking Antimuscarinic Drugs for Overactive Bladder:** Administer with caution in these patients because of the risk of urinary retention.
- **Patients Taking Drugs Metabolized by CYP2D6:** It is moderate inhibitor of CYP2D6. Appropriate monitoring is recommended and dose adjustment may be necessary for a narrow therapeutic index CYP2D6 substrates.

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.

Storage Conditions

Store in a cool and dry place, away from light. Keep out of the reach of children.

Commercial Pack

Mirabeg 25 : Each box contains 2 blister packs of 10 Tablets.

Mirabeg 50 : Each box contains 2 blister packs of 10 Tablets.

Manufactured by:

 **GENERAL**
Pharmaceuticals Ltd.
Kaliakair, Gazipur, Bangladesh

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