Miraflo® 25

Mirabegron Extended Release Tablet

DESCRIPTION

Miraflo® is a preparation of Mirabegron. 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.

INDICATIONS

Miraflo® is 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 the dose may be increased to 50 mg once daily. For Patients with Severe Renal Impairment or Patients with Moderate Hepatic Impairment, maximum dose is 25 mg once daily. **Miraflo®** should be taken with water, swallowed whole and should not be chewed, divided or crushed.

CONTRAINDICATIONS

None

SIDE EFFECTS

- Hypertension
- Nasopharyngitis
- Urinary tract infection
- Headache

PRECAUTION AND WARNING

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 risk of urinary retention.

Patients Taking Drugs Metabolized by CYP2D6: It is a moderate CYP2D6 inhibitor. Appropriate monitoring and dose adjustment may be necessary for a narrow therapeutic index drugs metabolized by CYP2D6.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C

There are no adequate and well-controlled studies using Mirabegron in pregnant women. Mirabegron 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 Mirabegron treatment are encouraged to contact their physician.

It is not known whether Mirabegron is excreted in human milk. So a decision should be made whether to discontinue nursing or to discontinue the drug considering the importance of the drug to the mother/ the risk benefit ratio of the patients.

PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Miraflo® 25 Tablet: Box containing 1 strip of 10 tablets. Each extended release tablet contains Mirabegron INN 25 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

GAZIPUR, BANGLADESH

® REGD.TRADEMARK

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