Mirader™ 25

Mirabegron 25 mg

Composition:
Each extended release tablet contains Mirabegron INN 25 mg.

Indication:
Mirabegron (**Mirader**™) is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

Pharmacology:
Mirabegron (**Mirader**™) is the first beta-3 adrenoceptor agonist. It exerts its effect via a dual mechanism, both directly acts on the bladder smooth muscle and also via the sensory nervous system, it increases the levels of cyclic adenosine monophosphate (cyclic AMP) and leads to relaxation of the detrusor smooth muscle during storage phase of urinary bladder fill-void cycle by activation of beta-3 adrenoceptor which increase bladder capacity.

Dosage and administration:
Starting dose of Mirabegron (**Mirader**™) is 25 mg once daily with or without food. Mirabegron (**Mirader**™) 25 mg is effective within 8 weeks. Based on individual patient efficacy and tolerability the dose may be increased to 50 mg once daily. Mirabegron (**Mirader**™) should be taken with water, swallowed whole and should not be chewed, divided, or crushed.
Patients with severe Renal Impairment or Patients with Moderate Hepatic Impairment: Maximum dose of Mirabegron (**Mirader**™) is 25 mg once daily.
Patients with End Stage Renal Disease (ESRD) or Patients with Severe Hepatic Impairment: Mirabegron (**Mirader**™) is not recommended.

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

Contraindications:
Mirabegron is contraindicated in patients who have known hypersensitivity reactions to mirabegron or any component of the tablet or hypertensive patients whose SBP >180, DBP >110

Drug interactions:
Mirabegron is CYP2D6 inhibitor and when used concomitantly with drugs metabolized by CYP2D6 (e.g., Metoprolol and Desipramine), especially narrow therapeutic index drugs, appropriate monitoring and possible dose adjustment of those drugs may be necessary.
When initiating a combination of Mirabegron and digoxin, lowest dose of digoxin should be prescribed

Warnings and precautions:
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. Administer with caution in Patients with Bladder Outlet Obstruction and in Patients taking Antimuscarinic Drugs for Overactive Bladder.

Use in specific populations:
Pregnancy: Pregnancy Category C. Use only if the benefit to the mother outweighs the potential risk to the fetus.
Nursing mothers: Mirabegron (**Mirader**™) is predicted to be excreted in human milk and is not recommended for use by nursing mothers.
Pediatric use: The safety and effectiveness of Mirabegron (**Mirader**™) in pediatric patients have not been established.
Geriatric use: No dose adjustment is recommended for elderly patients

Storage:
Protect from light and moisture. Store below 30^0 C. Keep ot of the reach of children.

Presentation:
Each box contains 20 extended release tablets in blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH