Iragon
Tablet

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

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. It is effective within 8 weeks. Based on individual efficacy and tolerability the dose may be increased to 50 mg once daily. It 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 is 25 mg once daily. Patients with end stage renal disease (ESRD) or patients with severe hepatic impairment : not recommended. Or, as directed by the registered physician.

Side effects : The most commonly reported side effect are : hypertension, urinary tract infection, headache and common cold symptoms (nasopharyngitis).

Contraindication : It is contraindicated in patients with hypersensitivity to Mirabegron or any other component of this product.

Drug interactions : Mirabegron may be interacts with the following drug : thioridazine, flecainide, propafenone, digoxin, warfarin.

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 : Mirabegron 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 using in pregnant women. It should be used during pregnancy only if the potential benefit to the patient outweighs the risk to the fetus. It is not known whether this tablet is excreted in human milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Overdose : Symptomatic and supportive treatment should be recommended.

Storage : Store below 25° C in a dry place.

Packing : Iragon : Each box contains 2 x 14's tablets in a blister pack.