

Only for the use of Medical Professionals

Miragon®

Mirabegron

Description

Miragon® is a preparation of Mirabegron which 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.

Indications

Miragon® 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 of mirabegron is 25 mg once daily with or without food up to 8 weeks. Maximum dose is 50 mg once daily.

Use in hepatic impairment patient: No dose adjustment is necessary in patients with mild hepatic impairment. In patients with moderate hepatic impairment, the daily dose of mirabegron should not exceed 25 mg. Mirabegron is not recommended for use in severe hepatic impairment patients.

Use in renal impairment patient: No dose adjustment is necessary in patients with mild or moderate renal impairment. In patients with severe renal impairment, the daily dose of mirabegron should not exceed 25 mg. Mirabegron is not recommended for use in end stage renal disease.

Use in pediatric patient: The safety and effectiveness of mirabegron in pediatric patients have not been established.

Use in pregnancy & lactation

Pregnancy

Mirabegron is a pregnancy category C. Mirabegron should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

It is not known whether mirabegron is excreted in human milk. Caution should be exercised when mirabegron is administered to a nursing woman.

Side effects

Most common side effects of mirabegron are increased blood pressure, urinary retention, common cold symptoms, urinary tract infection and headache.

Contraindications

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

Warnings & Precautions

Mirabegron can increase blood pressure thus it 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.

Drug interactions

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. When initiating a combination of mirabegron and digoxin, monitor serum digoxin concentrations to titrate digoxin dose to desired clinical effect.

Overdose

In the event of overdosage pulse rate, blood pressure and ECG monitoring is recommended. Treatment for overdosage should be symptomatic and supportive.

Pharmaceutical precautions

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

Presentation

Miragon® 25 tablet: Each prolonged release tablet contains Mirabegron INN 25 mg.

Package quantities

Miragon® 25 tablet: Carton of 30 tablets in blister pack.

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