

Maturex™

Dapoxetine Tablet

Presentation

Maturex™ 30 Tablet: Each tablet contains Dapoxetine Hydrochloride INN equivalent to Dapoxetine 30 mg.

Maturex™ 60 Tablet: Each tablet contains Dapoxetine Hydrochloride INN equivalent to Dapoxetine 60 mg.

Description

Dapoxetine tablet belongs to the pharmacotherapeutic group of Selective Serotonin Reuptake Inhibitors (SSRIs). The mechanism of action of dapoxetine in premature ejaculation is linked to the inhibition of neuronal reuptake of serotonin and the subsequent potentiation of the neurotransmitter's action in the pre- and post synaptic receptors, and delays the ejaculatory process. Dapoxetine tablet is rapidly absorbed and maximum plasma concentration reach approximately 1-2 hours after tablet intake. It has rapid elimination as evidenced by a low concentration 24 hours after dosing.

Indications and Usage

Dapoxetine tablet is indicated for the treatment of premature ejaculation in men from 18 to 64 years of age.

Dosage and Administration

The recommended starting dose of Dapoxetine tablet for all patients is 30 mg, taken as needed approximately 1 to 3 hours prior to sexual activity. The maximum recommended dosing frequency is once in every 24 hours.

Side Effects

Dizziness, headache, nausea, increased blood pressure, anxiety, restlessness, dry mouth, erectile dysfunction may be associated with the active components of Dapoxetine.

Contraindications

Dapoxetine tablet is contraindicated if patient has hypersensitivity to the active substances or any of the excipients, patients with heart failure, significant IHD and valvular heart disease. It is also contraindicated in moderate to severe hepatic impairment and severe renal impairment.

Precautions

Dapoxetine tablet is only indicated in men with premature ejaculation. Concomitant treatment with other SSRIs, SNRIs, TCAs, MAOIs, thioridazine or any of the herbal products should not be administered within 7 days after dapoxetine has been discontinued. Caution is advised in all patients with mild to moderate renal failure, orthostatic hypotension, cardiovascular disease, mania and concomitant treatment with CYP3A4 and CYP2D6 inhibitors.

Use in pregnancy and lactation: Dapoxetine is not indicated for use by women. It is not known either dapoxetine or its metabolites are excreted through human breast milk.

Overdose

There have been no reports of overdose during clinical trial.

Storage

Store at a cool temperature, away from light. Keep out of reach of children.

Commercial Pack

Maturex™ 30 Tablet: Each box containing 20 tablets in 10 X 2 Alu-Alu strips.

Maturex™ 60 Tablet: Each box containing 10 tablets in 10 X 1 Alu-Alu strip.

Manufactured by
 **Incepta Pharmaceuticals Ltd**
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