

Only for the use of Medical Professionals



Description

Daxelin® is a preparation of Dapoxetine Hydrochloride which is a selective serotonin reuptake inhibitor (SSRI). The mechanism of action of Dapoxetine in premature ejaculation is presumed to be linked to the inhibition of neuronal reuptake of serotonin and the subsequent potentiation of the neurotransmitter's action at pre and post synaptic receptors.

Indications and uses

Daxelin® is indicated for the treatment of -

- Premature ejaculation
- Personal distress or interpersonal difficulty as a consequence of premature ejaculation
- Poor control over ejaculation

Dosage & administration

Adult men (18 to 64 years of age)

The recommended starting dose of Daxelin® for all patients is 30 mg, taken as needed approximately 1 to 3 hours prior to sexual activity. If the effect of 30 mg is insufficient and the side effects are acceptable, the dose may be increased to the maximum recommended dose of 60 mg. The maximum recommended dosing frequency is one dose every 24 hours.

Elderly (age 65 years and over)

Safety and efficacy of Dapoxetine have not been established in patients age 65 years and over as limited data are available in this population.

Children and adolescents

Dapoxetine is not recommended for patients under 18 years of age

Patients with renal impairment

No dose adjustment is required but caution is advised in patients with mild or moderate renal impairment. Dapoxetine is not recommended for use in patients with severe renal impairment.

Patients with hepatic impairment

No dose adjustment is required in patients with mild hepatic impairment. Dapoxetine is contraindicated in patients with moderate and severe hepatic impairment.

Pregnancy and lactation

Pregnancy

Dapoxetine is pregnancy category C. Dapoxetine is not indicated for use by women. There are no adequate and well-controlled studies of Dapoxetine in pregnant women.

Lactation

Dapoxetine is not indicated for use by women. It is not known if either Dapoxetine or its metabolites are excreted in human breast milk.

Side effects

The most common reported side effects are loss of consciousness, orthostatic hypotension, headache, dizziness, nausea, diarrhoea, insomnia and fatigue.

Contraindications

Dapoxetine is contraindicated in patients with known hypersensitivity to Dapoxetine or to any of the excipients. It is also contraindicated in patients with heart failure, conduction abnormalities (second or third degree AV block or sick sinus syndrome) not treated with a permanent pacemaker, significant ischemic heart disease or significant valvular disease.

Precautions

General

Dapoxetine is only indicated in men with premature ejaculation. Safety has not been established and there are no data on the ejaculation-delaying effects in men without premature ejaculation.

Use with recreational drugs

Patients should be advised not to use Dapoxetine in combination with recreational drugs with serotonergic activity such as ketamine, methylenedioxymethamphetamine (MDMA) and lysergic acid diethylamide (LSD) because these may lead to potentially serious reactions if combined with Dapoxetine.

Syncope

The occurrence of syncope and possibly prodromal symptoms appears dose dependent as demonstrated by higher incidence among patients treated with doses higher than 60 mg, the recommended maximum daily dose.

Orthostatic hypotension

An orthostatic test should be performed before initiating therapy. In case of a history of documented or suspected orthostatic reaction, treatment with Dapoxetine should be avoided.

Warning

Combining alcohol with Dapoxetine may increase alcohol related neurocognitive effects and may also enhance neurocardiogenic adverse events such as syncope, thereby increasing the risk of accidental injury; therefore, patients should be advised to avoid alcohol while taking Dapoxetine.

Drug interactions

Dapoxetine should not be used in combination or concomitantly with CYP3A4 inhibitors such as ketoconazole, itraconazole, ritonavir, saquinavir, telithromycin, nefazodone, nefinavir, atazanavir, etc. It may also interact with SSRIs, MAOIs, thioridazine, serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs) and other serotonergic medicinal/herbal products.

Overdose

There were no unexpected events of overdose is reported with daily doses up to 240 mg (two 120 mg doses given 3 hours apart). In general, symptoms of overdose with SSRIs include serotonin-mediated adverse reactions such as somnolence, gastrointestinal disturbances such as nausea and vomiting, tachycardia, tremor, agitation and dizziness. In cases of overdose, standard supportive measures should be adopted as required. Due to high protein binding and large volume of distribution of Dapoxetine, forced diuresis, dialysis, hemoperfusion and exchange transfusion are unlikely to be of benefit. No specific antidotes for Dapoxetine are known.

Pharmaceutical precautions

Store in a cool & dry place protected from light. Keep away from the reach of children.

Presentation

Daxelin® 30 tablet: Each coated tablet contains Dapoxetine 30 mg as Hydrochloride INN.

Daxelin® 60 tablet: Each coated tablet contains Dapoxetine 60 mg as Hydrochloride INN.

Package quantities

Daxelin® 30 tablet: Carton of 12 tablets in blister pack.

Daxelin® 60 tablet: Carton of 8 tablets in blister pack.

® Registered Trade Mark



ACI Limited
Narayanganj, Bangladesh