

Susten™

Dapoxetine Hydrochloride INN

COMPOSITION

Susten™ 30 Tablet: Each film coated tablet contains Dapoxetine 30 mg as Dapoxetine Hydrochloride INN.

INDICATION

Indicated for the treatment of premature ejaculation (PE) in men 18 to 64 years of age, who have all of the following:

- Persistent or recurrent ejaculation with minimal sexual stimulation before, on or shortly after penetration and before the patient wishes.
- Marked personal distress or interpersonal difficulty as a consequence of PE and poor control over ejaculation.

DOSAGE & ADMINISTRATION

Adult men (18 to 64 years of age) : The recommended starting dose 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.

OVER DOSAGE

There were no unexpected adverse events in a clinical pharmacology study of Dapoxetine with daily doses up to 240 mg. 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.

SIDE EFFECTS

Dizziness, Headache, Somnolence, Tremor, Blurred vision, Tinnitus, Sinus congestion, Nausea, Diarrhea, Abdominal pain, Dry mouth, Fatigue, Insomnia, Hypertension.

CONTRAINDICATION

- Patients with known hypersensitivity to Dapoxetine Hydrochloride.
- Patients with significant pathological cardiac conditions such as heart failure (NYHA class II-IV), 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.
- Concomitant treatment with monoamine oxidase inhibitors (MAOIs), thioridazine. Similarly, MAOIs or thioridazine should not be administered within 7 days after Dapoxetine has been discontinued.
- Concomitant treatment with serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs) or other medicinal/herbal products with serotonergic effects or within 14 days of discontinuing treatment with these medicinal/herbal products.

DRUG INTERACTION

CNS active medicinal products: The use of Dapoxetine in combination with CNS active medicinal products has not been systematically evaluated in patients with premature ejaculation. Consequently, caution is advised if the concomitant administration of Dapoxetine and such medicinal products is required. PDE5 inhibitors: Tadalafil did not affect the pharmacokinetics of Dapoxetine. Sildenafil caused slight changes in Dapoxetine pharmacokinetics, which are not expected to be clinically significant. However, Dapoxetine should be prescribed with caution in patients who use PDE5 inhibitors due to possible reduced orthostatic tolerance. Tamsulosin: Concomitant administration of single or multiple doses of 30 mg or 60 mg Dapoxetine to patients receiving daily doses of Tamsulosin did not result in changes in the pharmacokinetics of Tamsulosin. However, Dapoxetine should be prescribed with caution in patients who use alpha adrenergic receptor antagonists due to possible reduced orthostatic tolerance. Warfarin: There are no data evaluating the effect of chronic use of Warfarin with Dapoxetine; therefore, caution is advised when Dapoxetine is used in patients taking Warfarin chronically.

Ethanol: Concomitant use of alcohol and Dapoxetine could increase the chance or severity of adverse reactions such as dizziness, drowsiness, slow reflexes, or altered judgment. Combining alcohol with Dapoxetine may increase these alcohol-related 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.

PREGNANCY AND LACTATION

Dapoxetine is not indicated for use by women.

STORAGE

Store below 30°C. Protect from light and moisture. Keep out of reach of children.

HOW SUPPLIED

Susten™ 30 Tablet: Each box contains 10 tablets.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH