Solider™

Solifenacin Succinate INN

Composition

Solider™ 5 Tablet: Each film coated tablet contains Solifenacin Succinate INN 5 mg.
Solider™ 10 Tablet: Each film coated tablet contains Solifenacin Succinate INN 10 mg.

Pharmacology

Solifenacin is a competitive muscarinic receptor antagonist. Muscarinic receptors play an important role in several major cholinergically mediated functions, including contractions of urinary bladder smooth muscle and stimulation of salivary secretion. After oral administration, peak plasma levels of Solifenacin are reached within 3 to 8 hours. The absolute bioavailability of Solifenacin is approximately 90%. Solifenacin is extensively metabolized in the liver. The primary pathway for elimination is CYP3A4. Because of a long elimination half life, once-a-day dose can offer 24-hour control of the urinary bladder smooth muscle tone.

Indications

Symptomatic treatment of urge incontinence and increased urinary frequency and urgency as may occur in patient with overactive bladder syndrome.

Dosage & Administration

The recommended dose of Solifenacin Succinate is 5 mg (One **Solider**™ 5) once daily. If the 5 mg dose is well tolerated, the dose may be increased to 10 mg (one **Solider**™ 10) once daily. Solifenacin Succinate should be taken with liquids and swallowed whole. Solifenacin Succinate (**Solider**™ Tablet) can be administered with or without food, without regard to meals. The maximum effect can be determined after 4 weeks at the earliest.

Dosing considerations

Dose Adjustment in Renal Impairment: For patients with severe renal impairment (CrCl < 30 mL/min), a daily dose of Solifenacin Succinate greater than 5 mg is not recommended. Solifenacin Succinate is contraindicated in dialysis dependent patients. *Dose Adjustment in Hepatic Impairment:* For patients with moderate hepatic impairment (Child-Pugh B), a daily dose of Solifenacin Succinate greater than 5 mg is not recommended. Use of Solifenacin Succinate in patients with severe hepatic impairment (Child Pugh C) is not recommended. *Dose Adjustment with CYP450, 3A4 Inhibitors:* When administered with therapeutic doses of ketoconazole or other potent CYP450, 3A4 inhibitors, e.g. Ritonavir, Nelfinavir, Itraconazole a daily dose of Solifenacin Succinate should be maintained at, or dropped to, 5 mg daily.

Contraindication

Contraindicated in patients with hypersensitivity to Solifenacin, angioedema, urinary retention, dependent on dialysis, gastroparesis or uncontrolled narrow angle glaucoma and in patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the product.

Adverse effects

Side effects of antimuscarinic agents are dry mouth, constipation, blurred vision (accommodation abnormalities), urinary retention and dry eyes.

Warning

Solifenacin Succinate 5 mg should be used with caution in patients with: clinically significant bladder outlet obstruction at risk of urinary retention, GI obstructive disorders, risk of decreased GI motility & should not exceed 5 mg. Patient with severe renal impairment (CrCl < 30 mL/min), moderate hepatic impairment (Child-Pugh B), a daily dose of Solifenacin Succinate greater than 5 mg is not recommended. *Prolongation of QT Interval:* 30-mg daily dosage associated with more pronounced prolongation of QT interval than 10-mg daily dosage. *Controlled Angle-closure Glaucoma:* Use with caution in patients being treated for angle-closure glaucoma.

Drug-Drug Interactions

Drugs metabolized by cytochrome P450: At therapeutic concentrations, Solifenacin does not inhibit CYP1A1/2, 2C9, 2C19, 2D6, or 3A4 derived from human liver microsomes. *CYP3A4 inhibitors:* In vitro drug metabolism studies have shown that Solifenacin is a substrate of CYP3A4. Inducers or inhibitors of CYP3A4 may alter Solifenacin pharmacokinetics. Following the administration of 10 mg of Solifenacin in the presence of 400 mg of ketoconazole, a potent inhibitor of CYP3A4, the mean C and AUC of Solifenacin increased by 1.5 and 2.7 fold, respectively. Therefore, it is recommended not to exceed a 5 mg daily dose of Solifenacin when administered with therapeutic doses of ketoconazole or other potent CYP3A4 inhibitors. *Oral Contraceptives:* In the presence of Solifenacin there are no significant changes in the plasma concentrations of combined oral contraceptives (ethinyl estradiol/levonorgestrel). *Warfarin & Digoxin:* Solifenacin has no significant effect on the pharmacokinetics of R-warfarin or S-warfarin & Digoxin.

Use in Pregnancy and Lactation

Pregnancy Category C. There are no adequate and well-controlled studies investigating the effects of Solifenacin Succinate in pregnant women. Animal reproduction studies are not always predictive of human response; therefore, Solifenacin Succinate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Women of childbearing potential should be considered for treatment only if using adequate contraception. Lactating Mother – It is not known whether Solifenacin is excreted in human milk. Because many drugs are excreted in human milk, Solifenacin should not be administered during nursing.

Pediatric Use - Safety and efficacy is not established in children below 18 years of age.

Storage condition

Protected from light & moisture (Store below 30° C). Keep all medicines out of reach of children.

How supplied

Solider™ 5: Each box contains 30 tablets in blister packs.
Solider™ 10: Each box contains 10 tablets in blister packs.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH