

Urginafect 5 mg

Film-coated Tablets

Company Name:

Medizen Pharmaceutical Industries

Generic Name:

Solifenacin succinate 5 mg

Dosage Form:

Film-coated tablets

Composition:

Each tablet contains:

Active ingredients:

Solifenacin succinate 5 mg.

Inactive ingredients:

Lactose anhydrous, starch, talc, magnesium stearate, croscarmellose, titanium dioxide PEG 8000, yellow ferric oxide.

Pharmacological Action:

Solifenacin is a competitive muscarinic receptor antagonist. Muscarinic receptors play an important role in several major cholinergically mediated functions including contractions of the urinary bladder's smooth muscle and stimulation of secretions of the salivary glands.

Pharmacokinetics:

Absorption:

After oral administration, the plasma levels of solifenacin are reached within 3 to 8 hours. The absolute bioavailability of solifenacin is approximately 90%, and plasma concentrations of solifenacin are proportional to the dose administered.

There is no significant effect of food on the pharmacokinetics of solifenacin.

Distribution:

Solifenacin is approximately 98% bound to human plasma proteins.

Metabolism:

Solifenacin is extensively metabolized in the liver.

Excretion:

Major metabolites have been identified in urine and in feces. The elimination half-life of solifenacin following chronic dosing is approximately 45-68 hours.

Indications and Usage:

Solifenacin is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency.

Dosage and Administration:

The recommended dose of Solifenacin is 5mg (one tablet) once daily. If the 5 mg dose is well tolerated, the dose may be increased to 10 mg once daily.

Solifenacin should be taken with liquids and swallowed whole. Solifenacin can be

administered with or without food.

Drug Interactions:

CYP3A4 Inhibitors: Inducers or inhibitors of CYP3A4 may alter solifenacin pharmacokinetics.

Ketoconazole Interaction: 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.

Contraindications:

Solifenacin is contraindicated in patients who have hypersensitivity to solifenacin or other components of the product.

Precautions:

Bladder Outflow Obstruction: Solifenacin, like other anticholinergic drugs, should be administered with caution to patients with clinically significant bladder outflow obstruction because of the risk of urinary retention.

Gastrointestinal Obstructive Disorders And Decreased Gastrointestinal Motility: Solifenacin, like other anticholinergics, should be used with caution in patients with decreased gastrointestinal motility.

Controlled Narrow-angle Glaucoma: Solifenacin should be used with caution in patients being treated for narrow-angle glaucoma.

Reduced Renal Function: Solifenacin should be used with caution in patients with reduced renal function.

Reduced Hepatic Function: Solifenacin should be used with caution in patients with reduced hepatic function.

Pregnancy and Nursing Mothers:

There are no adequate and well-controlled studies in pregnant women. Solifenacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether solifenacin is excreted in human milk so, solifenacin is not recommended during lactation unless the physician recommends it.

Adverse Reactions:

Hypersensitivity reactions including angioedema, rash, pruritis and urticaria. Confusion, hallucinations, blurred vision, constipation, abdominal pain and dry mouth may rarely occur. Heat prostration (due to decreased sweating) can occur when drugs such as solifenacin are used in a hot environment.

Package:

Carton box containing 1 or 2 pvdc/aluminum strips; each strip has 10 tablets.

Storage:

Keep out of reach of children.

Keep at a temperature not exceeding 30°C in a dry place.

Information for Patients:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please refer to your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others even if their

symptoms are the same as yours.

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