Solina-5

Tablet

DRUG INTERNATIONAL LTD.

Composition : **Solina-5 :** Each Film Coated Tablet Contains Solifenacin Succinate BP 5 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. It has a long duration of action. Solifenacin is a competitive muscarinic receptor antagonist with selectivity for the urinary bladder over salivary in vitro and in vivo. Solifenacin is also more potent in inhibiting carbachol-induced increases in interavesical pressure than in inhibiting slivary secretion.

Indications : Solifenacin is indicated for the Symptomatic treatment of urge incontinence and Increased urinary frequency and urgency as may occur in patient with overactive bladder Syndrome.

Dosage and administration : The recommended of Solifenacin Succinate is 5 mg once daily. If the 5 mg dose is well tolerated, the dose may be increased to 10 mg once daily. Solifenacin Succinate should be taken with liquid and swallowed whole. Solifenacin Succinate can be administered with of without food. The maximum effect can be determined after 4 weeks at the earliest. Or, as directed by the registered physician.

Contraindication : Solifenacin is contraindicated in patients with hypersensitivity to the drug or any other component of the product. Also contraindicated in patients with hypersensitivity to angioedema, urinary retention depended on dialysis, gastroparesis or uncontrolled narrow-angle glaucoma.

Precautions : Solifenacin Should be administered with caution to patients with clinically significant bladder outflow obstruction because of the risk of urinary retention, gastrointestinal motility and narrow-angle glaucoma and should not exceed 5 mg. Solifenacin Should be used with caution in patients with renal impairment, Doses of Solifenacin greater than 5 mg are not recommended in patients with severe renal impairment (CLcr <30mL/min).

Side effects : The most common side effects are: dry mouth, constipation, blurred vision (accommodation abnormalities), Dry eyes and Urinary retention.

Use in pregnacy and lactation : Pregnancy Category C. There are no adequate and well controlled studies in pregnant women. It 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. Because many drugs are excreted in human milk, Solifenacin should not be administered to a nursing woman.

Use in Child : Safety & effectiveness of Solifenacin succinate in Pediatric Patients below 10 years has not been estabilished.

Drug interactions : At therapeutic concentrations, Solifenacin does not inhibit CYP1A1/2, 2C9, 2C19, 2D6, or 3A4 derived from human liver microsomes. In vitro drug metabolism studies have shown that Solifenacin is a substrate of CYP3A4. Therefore, inducers of CYP3A4 may decrease the concentration of Solifenacin. Solifenacin has no significant effect on the pharmacokinetics of R-warfarin or S-warfarin.

Overdose : Overdosage with Solifenacin can potentially result in severe anticholinergic effects and should be treated accordingly. The highest dose ingested in an accidental overdose of Solifenacin Succinate was 280 mg in a 5-hour period. This case was associated with mental status changes. Some cases reported a decrease in the level of consciousness.

Storage : Store below 30°C in a dry place.

Packing : **Solina-5 :** Each box contains 1 x 14's tablets in blister pack.