Bladder Outflow Obstruction: 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. Doses of Solifenacin greater than 5 mg are not recommended in patients with severe renal impairment (CLr < 30 ml/min).

Reduced Hepatic Function: Solifenacin should be used with caution in patients with hepatic impairment. Doses of solifenacin greater than 5 mg are not recommended in patients with moderate hepatic impairment (Child-Pugh B). Solifenacin is not recommended for patients with severe hepatic impairment (Child-Pugh C).

Drug-Drug Interactions: Do not exceed a 5 mg daily dose of Solifenacin when administered with therapeutic doses of ketonozazole or other potent CYP3A4 inhibitors.

Patients with Congestive or Acquired QT Prolongation: A study of the effect of solifenacin on the QT interval in 76 healthy women, the QT prolonging effect appeared less with solifenacin 10 mg than with 30 mg (the maximum recommended dose), and the effect of solifenacin 30 mg did not appear as large as that of the positive control mosfloxacin at its therapeutic dose. This observation should be considered in clinical decisions to prescribe Solifenacin to patients with a known history of QT prolongation or patients who are taking medications known to prolong the QT interval.

Pregnancy: Teratogenic Effects; Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Solifenacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery: The effect of Solifenacin on labor and delivery in humans has not been studied.

Nursing Mothers: 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. A decision should be made whether to discontinue nursing or to discontinue Solifenacin in mothers.

Pediatric Use: The safety and effectiveness of Solifenacin in pediatric patients have not been established.

Geriatric Use: In placebo controlled clinical studies, similar safety and effectiveness were observed between older and younger patients treated with Solifenacin.

ADVERSE REACTIONS: Expected side effects of antimuscarinic agents are dry mouth, constipation, blurred vision (accommodation abnormalities), urinary retention, and dry eyes. The most common adverse events reported in patients treated with Solifenacin were dry mouth and constipation and the incidence of these side effects was higher in the 10 mg compared to the 5 mg dose group. The incidence and severity of adverse events were similar in patients who remained on drug for up to 12 months. Adverse events that were reported in randomized, placebo-controlled trials at an incidence greater than placebo and in 1% or more of patients treated with Solifenacin 5 or 10 mg once daily for up to 12 weeks are as follows.

Gastrointestinal Disorders: Dry Mouth, Constipation, Nausea, Vomiting, Hemorrhoids, Upper Gastrointestinal Tract Infections and Infestations: Urinary Tract Infection, Influenza, Pharyngitis

Nervous System Disorders: Dizziness, Eye Disorders: Vision Blurred, Dry Eyes

Renal and Urinary Disorders: Urolithiasis

General Disorders: Edema of Lower Limb, Fatigue, Hypertension and Cough

Psychiatric Disorders: Depression

DOSE AND ADMINISTRATION:

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

In patients with moderate hepatic impairment (Child-Pugh B) a dose of Solifenacin greater than 5 mg is not recommended.

No adjustment in Solifenacin is required in patients with severe hepatic impairment (Child-Pugh C).

The safety and effectiveness of Solifenacin in patients with severe hepatic impairment (Child-Pugh C) is not recommended.

Overdosage:

In overdose 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 duration of symptoms of 6-12 hours. No specific antidote is known. The QT interval prolongation effect appeared less with solifenacin 10 mg than with 30 mg (the maximum recommended dose), and the effect of solifenacin 30 mg did not appear as large as that of the positive control mosfloxacin at its therapeutic dose. This observation should be considered in clinical decisions to prescribe Solifenacin to patients with a known history of QT prolongation or patients who are taking medications known to prolong the QT interval.

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Labor and Delivery: The effect of Solifenacin on labor and delivery in humans has not been studied.

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