SOLIFENACIN SUCCINATE tablets are available as follows:

10 mg – light-pink to pink, round, standard, normal convex, film-coated, unscored tablets (NDC 23690-000-85; Imprint: 10); 20 mg – white to light-pink, round, standard, normal convex, film-coated, unscored tablets (NDC 23690-001-85; Imprint: 20).

Solifenacin succinate, like other anticholinergic drugs, should be administered with caution to patients with impaired hepatic function. In patients with moderate hepatic impairment (Child-Pugh B), the drug should be given with caution because of the potential for increased sedation and increased anticholinergic side effects. Solifenacin should be discontinued and appropriate therapy instituted if hepatic impairment worsens.

In patients with hepatic impairment, exposure to solifenacin succinate was higher in the 10 mg compared to the 5 mg dose group. In hepatic dysfunction, plasma levels were increased by about 60% compared to the 5 mg dose group. A lower dose may be appropriate for patients with hepatic dysfunction. The role of dose adjustment has not been determined.

Clinically significant acute renal impairment based on serum creatinine levels greater than 2 mg/dL or a decrease in serum creatinine of more than 20% has been observed in the clinical trials. If solifenacin succinate tablets are to be used in patients with severe renal impairment (creatinine clearance less than 15 mL/min), they should be treated at a dose of 5 mg/day to reduce the potential for serious adverse effects due to increased solifenacin exposure. Solifenacin should be discontinued and appropriate therapy instituted if renal impairment worsens.

In postmarketing experience, serious adverse reactions, including death, have been reported after solifenacin succinate overdose. The majority of these reports described patients who ingested multiple doses of solifenacin succinate. Reports of serious reactions included: QT prolongation; torsade de pointes, atrial fibrillation, tachycardia, palpitations; urinary retention; respiratory distress; pulmonary edema; blood pressure response; increase in salivation; dry mouth; and constipation. It is not known if solifenacin succinate tablets are safe and effective in patients with severe renal impairment. Solifenacin should be discontinued and appropriate therapy instituted if renal impairment worsens.

Solifenacin succinate tablets are indicated for the once-daily treatment of overactive bladder (OAB) in adults. Solifenacin succinate tablets are not indicated for the treatment of voiding difficulties in patients with neurogenic detrusor overactivity (NDO). Solifenacin succinate tablets are not indicated for the treatment of nocturnal enuresis.

The effectiveness of solifenacin succinate tablets compared to placebo has been demonstrated in studies of up to 6 months' duration. There is no information available on the use of solifenacin succinate tablets for more than 6 months. It is not known if solifenacin succinate tablets are safe and effective for use longer than 6 months.

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The duration of treatment with solifenacin succinate tablets is 5 mg once daily if the 5 mg dose was well tolerated, the dose may be increased to 10 mg once daily if the patient has not responded adequately to the 5 mg dose after 6 weeks of treatment. In patients who respond adequately to the 5 mg dose, the dose should be increased to 10 mg once daily if the patient has not responded adequately to the 5 mg dose after 4 weeks of treatment. The dose should be titrated to the lowest effective dose that controls symptoms.

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The most common side effects of solifenacin succinate tablets include:

- dry mouth
- constipation
- nausea
- blurred vision
- dizziness
- headache
- fatigue
- urination problems (such as feeling the need to urinate or having the urge to urinate before you can get to the bathroom)
- having continuous urine leakage (incontinence)

If you have any side effect that bothers you or that does not go away:

- Tell your doctor if you have any side effect that bothers you or that does not go away.
- You can ask your doctor or pharmacist for information about solifenacin succinate tablets. For more information, ask your doctor or pharmacist.

Tell your doctor or pharmacist if you have any medical conditions or problems:

- You can ask your doctor or pharmacist for information about solifenacin succinate tablets. For more information, ask your doctor or pharmacist.

# Medications and Other Information

## Medications

### Overactive Bladder Medications

#### Side Effects

- **dry mouth**
- **constipation**
- **nausea**
- **blurred vision**
- **dizziness**
- **headache**
- **fatigue**
- **urination problems (such as feeling the need to urinate or having the urge to urinate before you can get to the bathroom)**
- **having continuous urine leakage (incontinence)**

### Solifenacin Succinate Tablets

#### Active Ingredient

- **Solifenacin succinate**

#### inactive ingredients:

- colloidal silicon dioxide, crospovidone, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, lactose, and titanium dioxide. Additional: The 10 mg strength also contains Sirius Black B and iron oxide red, and iron oxide yellow.

### General Information

#### About Diaphragm Insert

- The diaphragm insert is a medical device used to help control bladder function in people with overactive bladder (OAB). It is inserted into the bladder through the urethra (the tube that carries urine out of the body) and is designed to help prevent the flow of urine during certain activities, such as coughing, sneezing, or laughing. It works by applying pressure to the bladder neck, which helps to close the bladder opening and prevent urine leakage.

### Inserting the Diaphragm Insert

1. **Wash your hands**
2. **Sit on the toilet**
3. **Place the diaphragm insert on the toilet seat**
4. **Insert the diaphragm insert into the urethra**
5. **Check the diaphragm insert**
6. **Return the diaphragm insert to the manufacturer**

### Removing the Diaphragm Insert

1. **Wash your hands**
2. **Sit on the toilet**
3. **Remove the diaphragm insert from the urethra**
4. **Return the diaphragm insert to the manufacturer**

### What is overactive bladder?

Overactive bladder (OAB) is a condition when you have urgent or frequent urges to urinate, especially when you are active or during the night. OAB can be intensified by coughing, sneezing, or laughing. OAB occurs when the bladder is not able to hold urine for too long or when the muscles that control urination are too active, causing the bladder to contract involuntarily, leading to urine leakage. OAB is a common condition, affecting millions of people worldwide.

### How to Treat OAB

There are several treatment options for OAB, including medication, behavioral therapies, and lifestyle changes.

- **Medications:** Anticholinergics (such as solifenacin succinate) are commonly used to treat OAB by blocking the effects of acetylcholine, a neurotransmitter that stimulates urination. Anticholinergics can reduce the frequency and urgency of urination and decrease urine leakage.

### Other Information

- **Diaphragm Insert:** A diaphragm insert is a medical device used to help control bladder function in people with overactive bladder (OAB). It is inserted into the bladder through the urethra (the tube that carries urine out of the body) and is designed to help prevent the flow of urine during certain activities, such as coughing, sneezing, or laughing. It works by applying pressure to the bladder neck, which helps to close the bladder opening and prevent urine leakage. The diaphragm insert is made of medical-grade silicone and is designed to be comfortable and easy to wear.

### Side Effects of Diaphragm Insert

- **dry mouth**
- **constipation**
- **nausea**
- **blurred vision**
- **dizziness**
- **headache**
- **fatigue**
- **urination problems (such as feeling the need to urinate or having the urge to urinate before you can get to the bathroom)**
- **having continuous urine leakage (incontinence)**

### Inserting the Diaphragm Insert

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2. **Sit on the toilet**
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