

<b>Patient Information</b> <b>Solifenacin succinate tablet (SOE-li-FEN-a-sin SUX-i-nate)</b>
Read the Patient Information that comes with solifenacin succinate before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or treatment.
<p><b>What is solifenacin succinate?</b></p> <p>Solifenacin succinate is a prescription medicine for <b>adults</b> used to treat the following symptoms due to a condition called <b>overactive bladder</b>:</p> <ul style="list-style-type: none"> <li>• Urge urinary incontinence: a strong need to urinate with leaking or wetting accidents</li> <li>• Urgency: a strong need to urinate right away</li> <li>• Frequency: urinating often</li> </ul> <p>Solifenacin succinate 5 mg and 10 mg tablets are not approved for use in children.</p>
<p><b>Who should not take solifenacin succinate?</b></p> <p><b>Do not</b> take solifenacin succinate if you:</p> <ul style="list-style-type: none"> <li>• are not able to empty your bladder (urinary retention)</li> <li>• have delayed or slow emptying of your stomach (gastric retention)</li> <li>• have an eye problem called “uncontrolled narrow-angle glaucoma”</li> <li>• are allergic to solifenacin succinate or any of the ingredients in solifenacin succinate. See the end of this leaflet for a complete list of ingredients.</li> </ul>
<p><b>What should I tell my doctor before taking solifenacin succinate?</b></p> <p><b>Before you take solifenacin succinate, tell your doctor if you:</b></p> <ul style="list-style-type: none"> <li>• have any stomach or intestinal problems or problems with constipation</li> <li>• have trouble emptying your bladder or you have a weak urine stream</li> <li>• have an eye problem called “narrow angle glaucoma”</li> <li>• have liver problems</li> <li>• have kidney problems</li> <li>• have a rare heart problem called “QT prolongation”</li> <li>• are pregnant or plan to become pregnant. It is not known if solifenacin succinate will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.</li> <li>• are breastfeeding or plan to breastfeed. It is not known if solifenacin succinate passes into your breast milk. You and your doctor should decide if you will take solifenacin succinate or breastfeed.</li> </ul> <p><b>Tell your doctor about all the medicines you take</b>, including prescription and nonprescription medicines, vitamins, and herbal supplements. Solifenacin succinate may affect the way other medicines work, and other medicines may affect how solifenacin succinate works.</p>

**REVIEWED**

By ARTURO OROZCO at 3:00 pm, Jul 27, 2021

**APPROVED**

By Marcus at 6:41 am, Jul 28, 2021

#### How should I take solifenacin succinate?

- Take solifenacin succinate exactly as your doctor tells you to take it.
- You should take 1 solifenacin succinate tablet 1 time a day.
- You should take solifenacin succinate with water and swallow the tablet whole.
- You can take solifenacin succinate with or without food.
- If you miss a dose of solifenacin succinate, begin taking solifenacin succinate again the next day. Do not take 2 doses of solifenacin succinate the same day.
- If you take too much solifenacin succinate, call your doctor or go to the nearest hospital emergency room right away.

#### What should I avoid while taking solifenacin succinate?

Solifenacin succinate can cause blurred vision or drowsiness. Do not drive or operate heavy machinery until you know how solifenacin succinate affects you.

#### What are the possible side effects of solifenacin succinate?

Solifenacin succinate may cause serious side effects including:

- **Serious allergic reaction.** Stop taking solifenacin succinate and get medical help right away if you have:
  - hives, skin rash or swelling
  - severe itching
  - swelling of your face, mouth or tongue
  - trouble breathing

The most common side effects of solifenacin succinate include:

- dry mouth
- constipation. Call your doctor if you get severe stomach area (abdominal) pain or become constipated for 3 or more days.
- urinary tract infection
- blurred vision

Other side effects have been observed with anticholinergic drugs such as solifenacin succinate and may include:

dry skin due to decreased sweating. Heat exhaustion or heat stroke can happen due to decreased sweating when solifenacin succinate is used in hot environments. Symptoms may include:

- decreased sweating
- dizziness
- tiredness
- nausea
- increase in body temperature

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of solifenacin succinate. For more information, ask your doctor or pharmacist.

**Call your doctor for medical advice about side effects.**  
**You may report side effects to FDA at 1-800-FDA-1088.**

#### How should I store solifenacin succinate?

- Store solifenacin succinate between 59°F to 86°F (15°C to 30°C). Keep the bottle closed.
- Safely throw away medicine that is out of date or no longer needed.

**Keep solifenacin succinate and all medicines out of the reach of children.**

#### General information about the safe and effective use of solifenacin succinate

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use solifenacin succinate for a condition for which it was not prescribed. Do not give solifenacin succinate to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about solifenacin succinate. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about solifenacin succinate that is written for health professionals.

#### What are the ingredients in solifenacin succinate?

**Active ingredient:** solifenacin succinate

**Inactive ingredients:** corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, and titanium dioxide with yellow ferric oxide (5 mg solifenacin succinate tablet) or red ferric oxide (10 mg solifenacin succinate tablet).

#### What is overactive bladder?

Overactive bladder occurs when you cannot control your bladder contractions. When these muscle contractions happen too often or cannot be controlled you can get symptoms of overactive bladder, which are urinary frequency, urinary urgency, and urinary incontinence (leakage).

#### Rx Only

Manufactured by:  
ScieGen Pharmaceuticals, Inc.  
Hauppauge, NY 11788

For more information, call ScieGen Pharmaceuticals, Inc. at 1-855-724-343

This Patient Information has been approved by the U.S. Food and Drug Administration.

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