

Patient Information
VESicare LS® (VES-ih-care LS)
(solifenacin succinate)
oral suspension

What is VESicare LS?

- VESicare LS is a prescription medicine for **children aged 2 years of age and older** with a condition called **neurogenic detrusor overactivity**. It is used to increase the amount of urine your bladder can hold and reduce urine leakage.

Who should not take VESicare LS?

Do not take VESicare LS if you:

- have delayed or slow emptying of your stomach (gastric retention).
- have an eye problem called “uncontrolled narrow-angle glaucoma”.
- are allergic to solifenacin succinate or any of the ingredients in VESicare LS. See the end of this leaflet for a complete list of ingredients.

Before you take VESicare LS, tell your doctor if you have any medical conditions, including if you:

- have any stomach or intestinal problems or problems with constipation.
- have trouble emptying your bladder or you have a weak urine stream.
- have liver problems.
- have kidney problems.
- have a heart problem called “QT prolongation”.
- are pregnant or plan to become pregnant. It is not known if VESicare LS will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if VESicare LS passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take VESicare LS.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VESicare LS may affect the way other medicines work, and other medicines may affect how VESicare LS works.

How should I take VESicare LS?

- Take VESicare LS exactly as your doctor tells you to take it.
- If you have questions about dosing, talk to your pharmacist for instructions on how to prepare and administer VESicare LS.
- Shake the bottle well before taking each dose.
- You should take VESicare LS by mouth 1 time a day.
- Use an oral dosing device, such as an oral syringe, to correctly measure your dose. Ask your pharmacist for an appropriate oral dosing device.
- You should take VESicare LS followed by water or milk. Avoid taking VESicare LS at the same time with food or other drinks, as this may result in a bitter taste.
- Do not take 2 doses of VESicare LS the same day. If you miss a dose of VESicare LS, take it as soon as possible. If it has been 12 hours since taking the last dose of VESicare LS, skip that dose and take the next dose at the usual time.
- If you take too much VESicare LS, call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking VESicare LS?

VESicare LS can cause blurred vision or drowsiness. Do not drive or operate heavy machinery until you know how VESicare LS affects you.

What are the possible side effects of VESicare LS?

VESicare LS may cause serious side effects including:

- **Serious allergic reaction.** Stop taking VESicare LS 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
- **Central Nervous System (CNS) effects.** Talk to your doctor right away if you get any of these side effects:
 - headache
 - confusion
 - hear voices, see things, or sense things that are not there (hallucinations)
 - sleepiness

The most common side effects of VESicare LS include:

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

Other side effects have been observed with anticholinergic medicines such as VESicare LS and may include:

- blurred vision
- dry eyes
- dry skin due to decreased sweating. Heat exhaustion or heat stroke due to decreased sweating can happen when anticholinergic medications such as VESicare LS are 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 VESicare LS. 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 VESicare LS?

- Store VESicare LS at room temperature, between 68°F to 77°F (20°C to 25°C) with the cap closed.
- Store VESicare LS in the original bottle.
- Throw away VESicare LS oral suspension 28 days (4 weeks) after first opening.
- Safely throw away VESicare LS that has expired or is unused.

Keep VESicare LS and all medicines out of the reach of children.

General information about the safe and effective use of VESicare LS.

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

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

What are the ingredients in VESicare LS?

Active ingredient: solifenacin succinate

Inactive ingredients: polacrillin potassium, methylparaben, propylparaben, propylene glycol, simethicone emulsion 30%, carbomer homopolymer Type B, xylitol, acesulfame potassium, natural orange flavor, sodium hydroxide, and purified water.

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For more information, call 1-800-727-7003.

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

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