PACKAGE LEAFLET: INFORMATION FOR THE USER

Solifenacin succinate 1 mg/ml Oral Solution

solifenacin succinate

Space for Pharma code

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (See section 4).

What is in this leaflet:

1. What Solifenacin succinate oral solution is and what it is used for
2. What you need to know before you take Solifenacin succinate oral solution
3. How to take Solifenacin succinate
4. Possible side effects
5. How to store Solifenacin succinate oral solution
6. Contents of the pack and other information

1. What Solifenacin succinate oral solution is and what it is used for

The active substance of solifenacin succinate oral solution belongs to the group of anticholinergics. These medicines are used to reduce the activity of an overactive bladder. This enables you to wait longer before having to go to the bathroom and increases the amount of urine that can be held by your bladder.

Solifenacin succinate is used to treat the symptoms of a condition called overactive bladder. These symptoms include: having a strong, sudden urge to urinate without prior warning, having to urinate frequently or wetting yourself because you could not get to the bathroom in time.

2. What you need to know before you take Solifenacin succinate oral solution

Do not take Solifenacin succinate oral solution
- if you have an inability to pass water or to empty your bladder completely (urinary retention)
- if you have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis).
- if you suffer from a muscle disease called myasthenia gravis, which can cause extreme weakness of certain muscles.
- if you suffer from increased pressure in the eyes, with gradual loss of eyesight (glaucoma).
- if you are allergic to solifenacin or any of the other ingredients of this medicine (listed in section 6).
- if you are undergoing kidney dialysis.
- if you have severe liver disease.
- if you suffer from severe kidney disease or moderate liver disease AND at the same time are being treated with medicines that may decrease the removal of solifenacin succinate from the body (for example, ketoconazole). Your doctor or pharmacist will have informed you if this is the case.

Inform your doctor if you have or ever had any of the above-mentioned conditions before treatment with solifenacin succinate starts.

Warnings and Precautions

Talk to your doctor or pharmacist before taking solifenacin succinate oral solution:
- if you have trouble emptying your bladder (bladder obstruction) or have difficulty in passing urine (e.g. a thin urine flow). The risk of accumulation of urine in the bladder (urinary retention) is much higher.
- if you have some obstruction of the digestive system (constipation).
- if you are at risk of your digestive system slowing down (stomach and bowel movements).

Your doctor will have informed you if this is the case.
- if you suffer from severe kidney disease.
- if you have moderate liver disease.
- if you have a stomach tear (hiatus hernia) or heartburn.
- if you have a nervous disorder (autonomic neuropathy).
- if you suffer from any condition which results in alterations of your heart rhythm, especially an abnormality known as QT prolongation.

Inform your doctor if you have or ever had any of the above-mentioned conditions before treatment with solifenacin succinate oral solution starts.

Before starting solifenacin succinate oral solution, your doctor will assess whether there are other causes for your need to pass urine frequently (for example heart failure (insufficient pumping power of the heart) or kidney disease). If you have a urinary tract infection, your doctor will prescribe you an antibiotic (a treatment against particular bacterial infections).

Children and adolescents

Solifenacin succinate oral solution is not to be used in children or adolescents under 18 years.

Other medicines and Solifenacin succinate oral solution:

Please tell your doctor or pharmacist if you are taking or have recently taken or might take other medicines.

It is especially important to inform your doctor if you are taking:
- other anticholinergic medicines, effects and side effects of both medications can be enhanced.
- Cholinergic medicines as they can reduce the effect of solifenacin succinate oral solution.
- medicines, like metoclopramide and cisapride, which make the digestive system work faster. Solifenacin succinate oral solution can reduce their effect.
- medicines, like ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem, which decrease the rate at which solifenacin succinate oral solution is broken down by the body
- medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which solifenacin succinate oral solution is broken down by the body.
- medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis).

Solifenacin succinate oral solution with food and drink

Solifenacin succinate oral solution can be taken with or without food, depending on your preference.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not use solifenacin succinate oral solution if you are pregnant unless clearly necessary.

Do not use solifenacin succinate oral solution if you are breast-feeding as solifenacin may get into your breast milk.

Driving and using machines

Solifenacin succinate oral solution may cause blurred vision and sometimes sleepiness or tiredness. If you suffer from any of these side effects, do not drive or operate machinery.

Solifenacin succinate oral solution contains liquid maltitol and sodium benzoate:

If you have been told by your doctor that you have an intolerance to some sugars (such as liquid maltitol (E965)), contact your doctor before taking this medicinal product.

This medicine contains 0.2 mg sodium benzoate (E211) in each ml.

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.

If you get solifenacin succinate oral solution in your eyes: If you get solifenacin succinate oral solution in your eyes, rinse and clean your eyes thoroughly with water.

3. How to take Solifenacin succinate oral solution

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take this medicine orally with a glass of water. You can take this medicine before or after a meal. It can be taken with or without food, according to your preference.

The usual dose is 5 mg per day. If you need to take a dose of 5 mg, you should use the enclosed 5 ml oral syringe together with the enclosed adaptor to attach the syringe to the bottle. This helps you to take a dose from the bottle.

If your doctor told you to take 10 ml (10 mg) per day, you will need to use the 5 ml oral syringe twice to administer the total amount of a 10 ml (10 mg) dose.

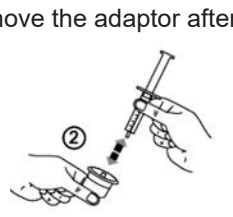
Method of administration

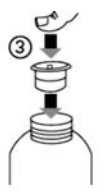
The dose of solifenacin succinate oral solution must be measured using the 5 ml graduated oral syringe supplied in the carton.

Open the bottle by pressing the cap while turning it anti-clockwise (figure 1).



Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottleneck (figure 3). Ensure it is well fixed. You do not need to remove the adaptor after use.





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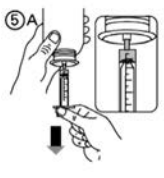
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Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).





Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upward to remove any possible bubbles (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).

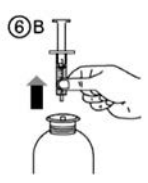






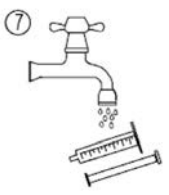
Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).





Empty the contents of the oral syringe into your mouth, please ensure that you are sitting upright and the plunger is pushed slowly to allow you to swallow the dose.

The steps above, as detailed in Figures 4 to 6B, will need to be repeated if a 10 ml (10 mg) dose is required.



After use close the bottle with the plastic screw cap (you do not need to remove the adaptor).

To clean the oral syringe, rinse with cold water only (figure 7), moving the plunger several times up and down to take up and expel the water.

Keep the bottle, the oral syringe, and the leaflet in the carton.

If you take more Solifenacin succinate oral solution than you should

If you have taken too much solifenacin succinate oral solution or if a child has accidentally taken solifenacin succinate oral solution, contact your doctor or pharmacist immediately.

Symptoms of overdose may include headache, dry mouth, dizziness, drowsiness and blurred vision, perceiving things that are not there (hallucinations), over-excitability, seizures (convulsions), difficulty breathing, elevated heart rate (tachycardia), accumulation of urine in the bladder (urinary retention) and dilated pupils (mydriasis).

If you forget to take Solifenacin succinate oral solution

If you forget to take a dose at the usual time, take it as soon as you remember, unless it is time to take your next dose. Never take more than one dose per day. If you are in doubt, always consult your doctor or pharmacist.

If you stop taking Solifenacin succinate oral solution

If you stop taking solifenacin succinate oral solution, your symptoms of overactive bladder may return or worsen. Always consult your doctor, if you are considering stopping the treatment.

If you have any further questions about the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience an allergic attack, or a severe skin reaction (e.g. blistering and peeling of the skin), you must inform your doctor or pharmacist immediately.

Angioedema (skin allergy that results in the swelling that occurs in the tissue just below the surface of the skin) with airway obstruction (difficulty in breathing) has been reported in some patients on solifenacin succinate. If angioedema occurs, solifenacin succinate should be discontinued immediately and appropriate therapy and/or measures should be taken.

Solifenacin succinate oral solution may cause the following other side effects:

Very common (may affect more than 1 in 10 people)
- dry mouth

Common (may affect up to 1 in 10 people)
- blurred vision
- constipation, nausea, indigestion with symptoms such as abdominal fullness, abdominal pain, burping, nausea, heartburn (dyspepsia) and stomach discomfort

Uncommon (may affect up to 1 in 100 people)
- urinary tract infection, bladder infection
- sleepiness, impaired sense of taste (dysgeusia)
- dry (irritated) eyes
- dry nasal passages
- reflux disease (gastro-oesophageal reflux), dry throat
- dry skin
- difficulty in passing urine
- tiredness, accumulation of fluid in the lower legs (oedema)

Rare (may affect up to 1 in 1,000 people)
- lodging of a large amount of hardened stool in the large intestine (faecal impaction)
- build-up of urine in the bladder due to inability to empty the bladder (urinary retention)
- dizziness, headache
- vomiting
- itching, rash

Very rare (may affect up to 1 in 10,000 people)
- hallucinations, confusion
- allergic rash

Not known (frequency cannot be estimated from the available data)
- decreased appetite, and high levels of blood potassium which can cause abnormal heart rhythm
- increased pressure in the eyes
- changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your
- heartbeat, faster heartbeat
- voice disorder
- liver disorder
- muscle weakness
- renal disorder

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Solifenacin succinate oral solution

Keep this medicine out of the sight and reach of children.

Do not use solifenacin succinate oral solution after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C in the original container.

After the first opening of the bottle, the solution can be stored for 30 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Solifenacin succinate oral solution contains

The active substance is solifenacin succinate. Each 1 ml of oral solution contains 1mg of solifenacin succinate corresponding to 0.75 mg of solifenacin.

The other ingredients are sodium benzoate (E211), sucralose (E955), liquid maltitol (E965), peppermint flavour, citric acid monohydrate, and purified water.

What does Solifenacin succinate oral solution looks like and contents of the pack

Solifenacin succinate oral solution is a clear, colourless liquid with a peppermint-type odour.

Solifenacin succinate oral solution is packaged in an amber-coloured polyethylene terephthalate (PET) bottle with a child-resistant closure, containing 150 ml of liquid product.

Each carton contains 1 bottle and a 5 ml oral syringe (graduated at every 0.5ml equivalent to 0.5mg) with an adaptor

zydus

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