Package leaflet: Information for the patient

Solifenacin succinate 10 mg film-coated tablets

solifenacin succinate

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

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

The active substance of Solifenacin succinate belongs to the group of medicines called 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

Do NOT take Solifenacin succinate:

- if you are unable 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 the muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles
- if you suffer from increased pressure in the eyes, with gradual loss of eye sight (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.

Tell your doctor if you have or have 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

- if you have trouble emptying your bladder (bladder obstruction) or have difficulty in passing urine (e.g. a thin urine flow). Risk of accumulation of urine in the bladder (urinary retention) is much higher
- if you have some obstruction of the digestive system (e.g. 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).

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

Before starting Solifenacin succinate, your doctor will check 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 an antibiotic (a treatment against particular bacterial infections).

Other medicines and Solifenacin succinate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important to tell your doctor if you are taking:

- other anticholinergic medicines. The effects and side effects of both medications can be increased.
- cholinergic medicines as they can reduce the effect of Solifenacin succinate.
- medicines, such as metoclopramide and cisapride, which make the digestive system work faster. Solifenacin succinate can reduce their effect.
- medicines such as ketoconazole and itraconazole (antifungals), ritonavir and nelfinavir (used to treat HIV), verapamil and diltiazem (used to treat heart conditions or high blood pressure), may decrease the rate at which Solifenacin succinate is broken down by the body
- medicines such as rifampicin (an antibacterial), phenytoin and carbamazepine (used to treat epilepsy), may increase the rate at which Solifenacin succinate is broken down by the body.
- medicines such as bisphosphonates (used to treat osteoporosis), may cause or worsen inflammation of the gullet (oesophagitis).

Solifenacin succinate with food and drink

Solifenacin succinate can be taken with or without food.

Pregnancy and breast-feeding

You should not take Solifenacin succinate if you are pregnant unless your doctor has told you to.

Do not take Solifenacin succinate if you are breast-feeding as solifenacin may get into your breast milk.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Solifenacin succinate 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 contains lactose.

If you have been told by your doctor that you have a rare hereditary problem of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption you should not take this medicine.

3. How to take Solifenacin succinate

Instructions for proper use
Adults

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

You should swallow the whole tablet with some liquid. It can be taken with or without food. Do not crush the tablets.

The recommended dose is 5 mg per day, unless your doctor told you to take 10 mg per day.

For appropriate dosing solifenacin succinate 5mg tablets may be available.

Children and adolescents

Solifenacin succinate is not to be given to children or adolescents under 18 years.

If you take more Solifenacin succinate than you should

If you have taken too much Solifenacin succinate or if a child has accidentally taken Solifenacin succinate, 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

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.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Solifenacin succinate

If you stop taking Solifenacin succinate, 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 on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Serious side effects

Stop taking this medicine and contact your doctor immediately if you experience any of the following:

- a severe allergic attack (skin rash; swollen eyes, lips, hands and feet; swelling of the mouth, throat or tongue, which can cause breathing and swallowing difficulties), or a severe skin reaction (e.g. blistering and peeling of the skin)

- angioedema (skin allergy that results in swelling in the tissue just below the surface of the skin) with airway obstruction (difficulty in breathing)

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, and heartburn (dyspepsia), 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, 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 heart beat
- voice disorder
- liver disorder
- muscle weakness
- renal disorder

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist 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 at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Solifenacin succinate

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

Do not use this medicine after the expiry date which is stated on the carton, bottle and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

6. Contents of the pack and other information

What Solifenacin succinate contains

- The active substance is solifenacin succinate 10 mg
- The other ingredients are: lactose anhydrous, hypromellose (E464), maize starch, magnesium stearate (E470b), macrogol (E1521), titanium dioxide (E171), talc (E553b) and ferric oxide Red (E172).

What Solifenacin succinate looks like and contents of the pack

Solifenacin succinate 10 mg film-coated tablets are light pink colored film-coated round biconvex tablets embossed with code 'RK76' on one side and plain on other side. The tablets are about 7.5 mm long.

Solifenacin succinate tablets are available in PVC/PVDC blister pack and 40 ml HDPE bottle pack.

Pack sizes in blisters
30, 50, 90 or 100 tablets

Pack sizes in bottles
30, 50, 90 or 100 tablets
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132JH Hoofddorp
The Netherlands

Manufacturers:
Terapia SA
124 Fabricii Street
400 632 Cluj-Napoca
Romania

Or

Alkaloida Chemical Company Zrt.
Kabay János u. 29, Tiszavasvári, H-4440,
Hungary

Or

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:
Netherlands: Solifenacinesuccinaat SUN
Germany: SOLIFENACIN BASICS

Spain: Solifenacina SUN
Poland: SILAMIL
United Kingdom: Solifenacin succinate

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