

PACKAGE LEAFLET

Package leaflet: Information for the patient
Solifenacin succinate 5 mg & 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 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 allergic to solifenacin succinate or any of the other ingredients of this medicine (listed in section 6).
- 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 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, 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.
- have some obstruction of the digestive system (constipation).
- are at risk of your digestive system slowing down (stomach and bowel movements). Your doctor will have informed you if this is the case.
- suffer from severe kidney disease.
- have moderate liver disease.
- have a stomach tear (hiatus hernia) or heartburn.
- have a nervous disorder (autonomic neuropathy).

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

Before starting Solifenacin succinate, 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 is not to be used in children or adolescents under 18 years.

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 inform your doctor if you are taking:

- other anticholinergic medicines, as the effects and side effects of both medications can be enhanced.
- cholinergics, as they can reduce the effect of solifenacin.
- medicines like metoclopramide and cisapride, which make the digestive system work faster. Solifenacin succinate can reduce their effect.
- medicines, like ketoconazole, itraconazole (medicines used to treat fungal infections), ritonavir, nelfinavir (medicines used to treat HIV infections) and verapamil, diltiazem (medicines used to treat high blood pressure and heart diseases). These medicines decrease the rate at which solifenacin succinate is broken down by the body.
- medicines like rifampicin (medicine used to treat tuberculosis and other bacterial infections) and phenytoin, carbamazepine (medicines used to treat epilepsy). These medicines may increase the rate at which solifenacin is broken down by the body.
- medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis).

If you are taking any other medicine, please ask your doctor if your medicine belongs to any of the above mentioned groups.

Solifenacin succinate with food and drink

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, 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 if you are pregnant unless clearly necessary. Do not use Solifenacin succinate if you are breast-feeding as solifenacin may get into your breast milk.

Driving and using machines

Solifenacin 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 an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Solifenacin succinate

Instructions for proper use

Always take this medicine exactly as your doctor or pharmacist 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, according to your preference. Do not crush the tablets.

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

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. Do not take a double dose to make up for a forgotten dose. If you are in doubt, always consult your doctor or pharmacist.

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.

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 (Solifenacin). If angioedema occurs, solifenacin succinate (Solifenacin) should be discontinued immediately and appropriate therapy and/or measures should be taken.

Solifenacin succinate may cause the following:

Very common side effects (may affect more than 1 in 10 people):

- dry mouth

Common side effects (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 side effects (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
- acid reflux (gastro-oesophageal reflux)
- dry throat
- dry skin
- difficulty in passing urine
- tiredness
- accumulation of fluid in the lower legs (oedema)

Rare side effects (may affect up to 1 in 1000 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 side effects (may affect up to 1 in 10,000 people):

- hallucinations, confusion.
- skin rash with severe itching and formation of small lumps (hives or urticaria).

Not known (cannot be estimated from the available data)

- decreased appetite, increased potassium concentration in the blood which can cause an abnormal heart rhythm.
- increased pressure in the eye.
- changes in the electrical activity of the heart (ECG), irregular heartbeat, palpitations of the heart, increased heart beat.
- voice problems.
- liver impairment.
- muscular weakness.
- kidney impairment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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

This medicinal product does not require any special storage conditions.

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 and blister after “EXP”. The expiry date refers to the last day of that month.

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

- Each Solifenacin succinate 5 mg film-coated tablets contains 5 mg of solifenacin succinate.
- Each Solifenacin succinate 10 mg film-coated tablets contains 10 mg of solifenacin succinate
- The other ingredients are lactose monohydrate, hydroxypropyl methylcellulose, magnesium stearate, HPMC 2910/Hypromellose (6mPas), titanium dioxide, triacetin, talc, iron oxide yellow (5 mg), iron oxide red (10 mg)
-

What Solifenacin succinate looks like and contents of the pack

Solifenacin succinate 5 mg film-coated tablets are light yellow coloured, round shaped, biconvex film-coated tablets debossed with ‘S5’ on one side and plain on other side.

Solifenacin succinate 10 mg film-coated tablets are light pink coloured, round shaped, biconvex film-coated tablets debossed with ‘S10’ on one side and plain on other side.

Solifenacin succinate tablets are supplied in blister packs of 10, 20, 30, 50 and 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
Luton, LU2 8DL
United Kingdom

Manufacturer

MIAS Pharma Limited
Suite 2, Stafford House
Strand Road, Portmarnock
Co.Dublin, Ireland

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings, Luton
LU2 8DL
United Kingdom

This leaflet was last revised in 11/2022 .