Package leaflet: Information for the patient

Solifenacin succinate 5 mg film-coated tablets 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

Solifenacin succinate contains the active substance solifenacin, which 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 or any of the other ingredients of this medicine (listed in section 6)
- have an inability to pass water or to empty your bladder completely (urinary retention)
- have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis)
- suffer from the muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles
- suffer or are at risk of suffering from increased pressure in the eyes, with gradual loss of eye sight (glaucoma)
- are undergoing kidney dialysis
- have severe liver disease
- 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 from the body (for example, ketoconazole). Your doctor or pharmacist will have informed you if this is the case.

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 (e.g.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.
- are taking certain medicines known as CYP3A4 inhibitors (such as ketoconazole) which may increase the amount of solifenacin in your blood
- have a stomach tear (hiatus hernia) or heartburn and/or are taking certain medicines (such as biphosphates) that can cause or worsen inflammation of the gullet.
- have a nervous disorder (autonomic neuropathy).
- suffer from changes in heart rhythm (seen in ECG) or have low potassium level in your blood.

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 bacterial 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 (such as atropine, oxybutynin, hydroxyzine, bupropion, dextromethorphan) as it may increase the effects and side effects of both medicines.
- Cholinergics (medicines such as carbachol and pilocarpine) as they can reduce the effect of solifenacin.
- medicines, like metoclopramide and cisapride, which make the digestive system work faster.
  Solifenacin can reduce their effect.
- medicines, like ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem, which decrease the rate at which solifenacin is broken down by the body
- medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which solifenacin is broken down by the body.

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.

Pregnancy
You should not use Solifenacin succinate if you are pregnant unless clearly necessary.

Breast-feeding
Do not use this medicine 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 medicine.

3. How to take Solifenacin succinate

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 tablet.

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

Patients with liver or kidney problems
If you suffer from severe kidney problems or moderate liver problems you should not take more than 5 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

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Description	Solifenacin_succinate_5mg_10mg_30			Date: 08 Feb 19		Time: 15:40	
Component Type	Leaflet	Pharma Code	1805	No. of colours	1	Page Count	1 / 2
Affiliate Item Code	1699598	SAP No.	N/A	Colours	Black		
Superceded Affiliate Item Code	N/A	Vendor Job No.	101874269/0120	Non-Print Colours			
TrackWise PR No.	1699598	Trackwise Proof No.	2	Equate CMYK with			
MA No.	PL 04569/1503 & PL 04569/1502	Client Market	United Kingdom				
Packing Site/Printer	Medis International (Bolatice - CZ)	Keyline/Drawing No.	PIL_155x520_update				
Supplier Code	11300529 MI-01	Barcode Info	N/A	Main Font	Myriad Pro	Body Text Size	10.5 pt
		3D Render ID	N/A	Dimensions	155 x 520 mm	Min Text Size used	10.5 pt
Sign-offs							

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(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. 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
If you stop taking Solifenacin succinate, your symptoms of overactive bladder may return or worsen. Always talk to 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 notice any of the following side effects, stop taking this medicine and contact your doctor or go to the nearest hospital casualty department straight away:
Very rare (may affect up to 1 in 10,000 people):
- 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.

Not known (frequency cannot be estimated from the available data):
- Allergic attack, or a severe skin reaction (e.g. blistering and peeling of the skin).

Solifenacin succinate 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, feeling sick (nausea), indigestion with symptoms such as abdominal fullness, abdominal pain, burping, nausea and heartburn (dyspepsia).

Uncommon (may affect up to 1 in 100 people):
- urinary tract infection or bladder infection with signs such as painful or burning sensation when passing urine, back pain, cloudy urine or blood in urine. Talk to your doctor if you suffer from these signs.
- sleepiness, impaired sense of taste (dysgeusia)
- dry (irritated) eyes
- dry nasal passages
- reflux disease (gastro-oesophageal reflux with symptoms such as heartburn, difficulty in swallowing, unpleasant sour taste at the top of your throat or the back of your mouth)
- 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)
- blockage in the lower intestine (colon)
- 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
- hives
- a rash with measeles-like round patches.

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 heart beat
- complete blockage in the bowel (intestinal obstruction (ileus))
- severe confusion, which may be associated with either reduced or increased activities, problems with sleeping pattern and seeing or hearing things that are not real (hallucinations)
- voice disorder
- liver disorder or changes in liver function which may be seen in blood test
- muscle weakness
- kidney disorder
- stomach discomfort
- redness and scaling of the skin (exfoliative dermatitis)
- feeling your heart beat, faster heart beat.

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 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.

For bottle pack only: After first opening, use within 100 days.

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

This medicine 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.
  Each film-coated tablet contains 5 mg of solifenacin succinate, corresponding to 3.8 mg solifenacin.
  Each film-coated tablet contains 10 mg of solifenacin succinate, corresponding to 7.5 mg solifenacin.
- The other ingredients are:
  Tablet core:
  Lactose monohydrate, maize starch, hypromellose (E464), talc, magnesium stearate (E572)
  Tablet coating:
  Hypromellose, titanium dioxide (E171), propylene glycol, iron oxide yellow (E172)
  Hypromellose, titanium dioxide (E171), propylene glycol, iron oxide red (E172), iron oxide yellow (E172)

What Solifenacin succinate looks like and contents of the pack
Yellow, film-coated, round biconvex tablet marked with "M" on one side and "SF" over "5" on the other side.

Pink, film-coated, round biconvex tablet marked with "M" on one side and "SF" over "10" on the other side.

Pack sizes:
Blister packs containing 3, 5, 10, 20, 30, 30 x 1, 50, 60, 90, 100, 200 tablets.
Bottle packs of 30, 50, 90, 100, 200, 250, 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mylan,
Potters Bar,
Hertfordshire,
EN6 1TL,
United Kingdom.

Manufacturers
Mylan Hungary Kft,
H-2900 Komárom,
Mylan utca 1,
Hungary.

Gerard Laboratories,
35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13,
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