

SOLIFENACIN SANDOZ®

Solifenacin succinate

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

Read this leaflet carefully before you start taking this medicine.

This leaflet answers some common questions about Solifenacin Sandoz.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Solifenacin Sandoz against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What Solifenacin Sandoz is used for

Solifenacin Sandoz is used to treat the symptoms of overactive bladder. These symptoms include needing to rush to the toilet to urinate without warning, needing to urinate frequently, or wetting yourself because you did not get to the toilet in time.

Solifenacin Sandoz belongs to a group of medicines called anticholinergic medicines. It works by acting on specialised cells to reduce the activity of your bladder and help you control your bladder.

Your doctor may have prescribed Solifenacin Sandoz for another

reason. Ask your doctor if you have any questions about why Solifenacin Sandoz has been prescribed for you.

Solifenacin Sandoz is available only with a doctor's prescription.

There is no evidence that Solifenacin Sandoz is addictive.

Before you take Solifenacin Sandoz

When you must not take it

Do NOT take Solifenacin Sandoz if you are allergic to medicines containing solifenacin or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take Solifenacin Sandoz if you:

- suffer from urinary retention (inability to urinate or empty your bladder completely)
- are undergoing haemodialysis
- have severe kidney disease or moderate liver disease and are also taking medicines that can decrease the removal of Solifenacin Sandoz from the body (see Taking other medicines)
- have severe liver disease
- have uncontrolled glaucoma (high pressure in the eyes, with gradual loss of eye sight)

- have myasthenia gravis, a disease of the muscles causing drooping eyelids, double vision, difficulty in speaking or swallowing and sometimes muscle weakness in the arms or legs
- have a blocked gastro-intestinal tract or other gastro-intestinal disorders such as ulcerative colitis or toxic megacolon.

Do not take Solifenacin Sandoz if the expiry date (EXP.) printed on the pack has passed.

Do not take Solifenacin Sandoz if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Do not give Solifenacin Sandoz to children.

Tell your doctor if you are pregnant.

Solifenacin Sandoz may affect your developing baby if you take it during pregnancy. Your doctor will decide if you should take it.

Do not take Solifenacin Sandoz if you are breastfeeding.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- low potassium levels or a family history of heart rhythm problems. Solifenacin Sandoz may have an effect on the electro-cardiogram (ECG - a heart tracing) and may add to the effect of other medicines on the ECG. You should advise your doctor of any other medicines you are currently

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taking, particularly those affecting the heart rhythm. Your doctor may wish to perform an ECG if you have any risks of having an abnormal heart rhythm.

- blockage to your bladder that causes difficulty urinating
- obstruction of the digestive system (constipation)
- glaucoma (high pressure in the eyes, with gradual loss of eye sight)
- hiatus hernia or gastric reflux or are currently being treated with some medicines (such as bisphosphonates) which may make your reflux worse
- autonomic neuropathy, a nerve problem which sometimes occurs with diabetes and can lead to diarrhoea, impotence or low blood pressure.
- severe kidney disease.
- moderate liver disease.

If you have not told your doctor about any of the above, tell him/her before you start taking Solifenacin Sandoz.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Solifenacin Sandoz, or may affect how well it works.

Some medicines can slow down the removal of Solifenacin Sandoz from the body. If you are taking any of the following, 5 mg a day is the maximum recommended dosage:

- some antifungal medicines such as ketoconazole, itraconazole
- ritonavir and nelfinavir, medicines to treat HIV infection.

If you are taking any of the above medicines and you also have severe kidney disease or moderate

liver disease, you should not take Solifenacin Sandoz.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Solifenacin Sandoz.

How to take Solifenacin Sandoz

How much to take

The usual dose is 5 to 10 mg of Solifenacin Sandoz once a day.

Your doctor will decide the most suitable dose for you.

Talk to your doctor or pharmacist if you feel that the effect of Solifenacin Sandoz is too strong or too weak.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take Solifenacin Sandoz

Try to take Solifenacin Sandoz at the same time each day. Solifenacin Sandoz is taken by mouth. It can be taken with or without food.

Swallow the tablets whole with a glass of water.

Do not crush or chew the tablets.

If you crush or chew Solifenacin Sandoz tablets, they may not work as well.

If you forget to take Solifenacin Sandoz

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take Solifenacin Sandoz for

To properly control your condition, Solifenacin must be taken every day.

Keep taking Solifenacin Sandoz for as long as your doctor recommends.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) if you think you or anyone else may have taken too much Solifenacin Sandoz. Do this even if there are no signs of discomfort or poisoning.

While you are taking Solifenacin Sandoz

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Solifenacin Sandoz.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Solifenacin Sandoz.

If you become pregnant while taking Solifenacin Sandoz, tell your doctor.

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not stop taking Solifenacin Sandoz, or lower the dose, without checking with your doctor.

Do not use Solifenacin Sandoz to treat any other conditions unless your doctor tells you to.

Do not give Solifenacin Sandoz to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Solifenacin Sandoz affects you.

Solifenacin Sandoz can sometimes cause blurred vision and less frequently drowsiness and fatigue.

Do not drive or operate machinery if you suffer from any of these side effects.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Solifenacin Sandoz.

Like all other medicines, Solifenacin Sandoz may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Stop taking Solifenacin Sandoz and tell your doctor as soon as possible if you experience:

- allergic reactions including swelling of the face, lips, throat or tongue, difficulty breathing

Tell your doctor as soon as possible if you notice any of the following:

- chest pain or tightness
- swelling of the feet or legs
- changes in electrical activity of the heart (ECG), irregular heartbeat (Torsade de Points)

Tell your doctor if you notice any of the following and they worry you:

- dry mouth
- nausea, vomiting
- constipation
- indigestion
- heartburn (dyspepsia)
- stomach discomfort
- urinary tract infection, bladder pain
- difficulty passing urine, inability to empty the bladder
- urgent need to urinate
- blurred vision
- inability to empty the bladder
- dry eyes
- tiredness
- muscle weakness
- accumulation of fluid (swelling) in the lower limbs (oedema)
- dizziness
- sore / dry throat
- cough
- headache
- sleepiness
- hallucination
- confusion
- depression
- fast heartbeat
- palpitations
- skin reactions such as rash, itching or hives.

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Some of these side effects (for example, changes in electrical activity of the heart or liver function) can only be found when your doctor does tests from time to time to check your progress.

After using Solifenacin Sandoz

Storage

Keep Solifenacin where children cannot reach out.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in a place where the temperature stays below 25°C.

Do not store Solifenacin Sandoz or any other medicine in the bathroom or near a sink.

Do not leave Solifenacin Sandoz in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Solifenacin Sandoz, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

PRODUCT DESCRIPTION

What it looks like

Solifenacin Sandoz comes in two strengths of tablets:

- Solifenacin Sandoz 5 mg tablets are round light yellow tablets with debossment "05" on one side.
- Solifenacin Sandoz 10 mg tablets are round light pink tablets with debossment "10" on one side and score line on the other side.

The 10 mg scored tablet can be divided into equal doses.

The film-coated tablets are available in PVC/Al blisters or polyethylene bottles (with a polypropylene screw cap and desiccant insert) packed in a carton box.

Each blister pack and bottle
contains 30 tablets.

*Not all presentations may be
marketed*

Ingredients

The active ingredient in Solifenacin
Sandoz is solifenacin succinate

- 5mg: each Solifenacin Sandoz
tablet contains 5 mg solifenacin
succinate
- 10 mg: each Solifenacin Sandoz
tablet contains 10 mg
solifenacin succinate.

The tablets also contain:

- maize starch
- lactose monohydrate
- hypromellose
- magnesium stearate
- macrogol 6000
- talc
- titanium dioxide
- iron oxide yellow (5 mg tablets
only)
- iron oxide red (10 mg tablets
only)

This medicine does not contain
sucrose, gluten, tartrazine or any
other azo dyes.

This medicine does contain lactose.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road,
Macquarie Park,
NSW 2113, AUSTRALIA
Tel: 1800 726 369

® = Registered Trademark

This leaflet was prepared in
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Australian Register Number

5 mg tablet: AUST R 311730
(blisters)

10 mg tablet: AUST R 311729
(blisters)

5 mg tablet: AUST R 311728
(bottle)

10 mg tablet: AUST R 311727
(bottle)

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