

SOLIFENACIN SANDOZ®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Solifenacin Sandoz?

Solifenacin Sandoz contains the active ingredient solifenacin succinate. Solifenacin Sandoz is used to treat the symptoms of overactive bladder.

For more information, see Section [1. Why am I using Solifenacin Sandoz?](#) in the full CMI.

2. What should I know before I use Solifenacin Sandoz?

Do not use if you have ever had an allergic reaction to solifenacin succinate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Solifenacin Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Solifenacin Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Solifenacin Sandoz?

- 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

More instructions can be found in Section [4. How do I use Solifenacin Sandoz?](#) in the full CMI.

5. What should I know while using Solifenacin Sandoz?

Things you should do	<ul style="list-style-type: none">• 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 should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Solifenacin Sandoz affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using Solifenacin Sandoz?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are allergic reactions including swelling of the face, lips, throat or tongue, difficulty breathing; chest pain or tightness; swelling of the feet or legs; changes in electrical activity of the heart (ECG), irregular heartbeat (Torsade de Points).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SOLIFENACIN SANDOZ®

Active ingredient(s): *solifenacin succinate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Solifenacin Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Solifenacin Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Solifenacin Sandoz?](#)
- [2. What should I know before I use Solifenacin Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Solifenacin Sandoz?](#)
- [5. What should I know while using Solifenacin Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Solifenacin Sandoz?

Solifenacin Sandoz contains the active ingredient solifenacin succinate. 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.

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.

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.

2. What should I know before I use Solifenacin Sandoz?

Warnings

Do not use Solifenacin Sandoz if:

- you are allergic to solifenacin succinate, 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. Always check the ingredients to make sure you can use this medicine.
- you suffer from urinary retention (inability to urinate or empty your bladder completely)

- you are undergoing haemodialysis
- you 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 Section [3. What if I am taking other medicines?](#))
- you have severe liver disease
- you have uncontrolled glaucoma (high pressure in the eyes, with gradual loss of eye sight)
- you 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
- you have a blocked gastro-intestinal tract or other gastro-intestinal disorders such as ulcerative colitis or toxic megacolon.
- the expiry date (Exp.) printed on the pack has passed.**
- the packaging is torn or shows signs of tampering.**

Check with your doctor if you:

- have any other 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 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.
- are allergic to any other medicines, foods, dyes or preservatives.

Do not give Solifenacin Sandoz to children.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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.

4. How do I use 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.**

When to take Solifenacin Sandoz

- Try to take Solifenacin Sandoz at the same time each day.

How to take Solifenacin Sandoz

- 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 use Solifenacin Sandoz

Solifenacin Sandoz should be used regularly at the same time each day. If you miss your dose at the usual time,

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

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

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 use too much Solifenacin Sandoz

If you think that you have used too much Solifenacin Sandoz, you may need urgent medical attention.

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Solifenacin Sandoz?

Things you should 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 should 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**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Solifenacin Sandoz affects you.

Solifenacin Sandoz may cause dizziness in some people.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • cough • headache • sleepiness • hallucination • confusion • depression • fast heartbeat • palpitations • skin reactions such as rash, itching or hives. 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • allergic reactions including swelling of the face, lips, throat or tongue, difficulty breathing • chest pain or tightness • swelling of the feet or legs • changes in electrical activity of the heart (ECG), irregular heartbeat (Torsade de Points) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or to Medsafe at pophealth.my.site.com/carmreportnz/s/. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Solifenacin Sandoz contains

Active ingredient (main ingredient)	solifenacin succinate
Other ingredients (inactive ingredients)	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)
Potential allergens	lactose

This leaflet was prepared in August 2024.

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Do not take this medicine if you are allergic to any of these ingredients.

What Solifenacin Sandoz looks like

Solifenacin Sandoz comes in two strengths of tablets.:

Solifenacin Sandoz 5 mg – round light yellow tablets with debossment “05” on one side.

Available in PVC/Al blisters or polyethylene bottles (with a polypropylene screw cap and desiccant insert) packed in a carton box.

Each blister pack contains 30 tablets (Aust R 311730).

Each bottle contains 30 tablets (Aust R 311728).

Solifenacin Sandoz 10 mg – 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.*

Available in PVC/Al blisters or polyethylene bottles (with a polypropylene screw cap and desiccant insert) packed in a carton box.

Each blister pack contains 30 tablets (Aust R 311729).

Each bottle contains 30 tablets (Aust R 311727).

Not all presentations may be marketed.

Who distributes Solifenacin Sandoz

Solifenacin Sandoz is supplied in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Solifenacin Sandoz is supplied in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel: 0800 726 369