

# Oxybutynin Sandoz®

*oxybutynin hydrochloride tablets*

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Oxybutynin Sandoz.

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

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

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What Oxybutynin Sandoz is used for

Oxybutynin Sandoz is used to decrease the urgency and the frequency of urination. Oxybutynin Sandoz works by relaxing the bladder smooth muscle and helps to decrease muscle spasm. This delays the initial desire and the urge to urinate.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

There is no evidence that Oxybutynin Sandoz is addictive.

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

Oxybutynin Sandoz is not recommended for use in children under the age of 5 years, as there have been no studies of its effects in children.

### Before you take Oxybutynin Sandoz

#### *When you must not take it*

**Do not take Oxybutynin Sandoz if you have an allergy to Oxybutynin Sandoz or any of the ingredients listed at the end of this leaflet under Product Description.**

**Do not take this medicine if you have or have had any of the following medical conditions:**

- angle closure glaucoma or shallow anterior chamber - disorders of the eye
- partial or complete intestinal blockage; stomach, intestinal or large bowel problems including colitis (inflammation of the colon)
- myasthenia gravis - a disease of the muscles
- urinary tract blockage
- severe bleeding.

**Do not take Oxybutynin Sandoz if you are pregnant or intend to become pregnant.**

The safety of the use of Oxybutynin Sandoz in women who are pregnant or may become pregnant has not been established.

**Do not take Oxybutynin Sandoz if you are breastfeeding or plan to breastfeed.**

Like most medicines, Oxybutynin Sandoz is not recommended while you are breastfeeding.

**Do not give Oxybutynin Sandoz to a child under 5 years, unless directed by the child's doctor or pharmacist.**

The safety and effectiveness of Oxybutynin Sandoz in children under 5 years have not been established.

**Use caution when giving Oxybutynin Sandoz to children age 5 years or older.**

Children are more sensitive to the effects of Oxybutynin Sandoz.

**Do not take this medicine after the expiry date printed on the pack or if the packaging shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

#### *Before you start to take it*

**Tell your doctor or pharmacist if you have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes.

**Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**

Your doctor can discuss with you the risks and benefits involved.

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

- liver, kidney or heart problems

- high blood pressure
- thyroid problems
- enlarged prostate gland
- autonomic neuropathy (a disorder of the nervous system)
- angle closure glaucoma or shallow anterior chamber - disorders of the eye
- partial or complete intestinal blockage; stomach, intestinal or large bowel problems including colitis (inflammation of the colon)
- myasthenia gravis - a disease of the muscles
- Parkinson's disease
- urinary tract blockage
- severe bleeding
- hiatus hernia (movement of the stomach up into the chest with heart burn)
- diarrhoea.

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Oxybutynin Sandoz.**

### *Taking other medicines*

**Tell your doctor or pharmacist 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 and Oxybutynin Sandoz may interfere with each other. These include:

- digoxin - used to treat diseases of the heart (irregular heart rate, chronic heart failure)
- L-dopa - used to treat a disease of the brain affecting movement (Parkinson's disease)
- phenothiazines - a group of anti-psychotic drugs
- butyrophenones - a group of anti-psychotic drugs
- tricyclic antidepressants - used to treat depression
- amantidine - used to treat viral infection
- hyoscine - a muscle relaxant

- prokinetic drugs - medicines used to promote stomach emptying
- some antihistamines - used to treat the symptoms of hayfever.

These medicines may be affected by Oxybutynin Sandoz, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking this medicine.

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## How to take it

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### *How much to take*

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

The usual adult dose is one 5mg tablet two to three times per day. Your doctor may reduce this dosage depending on your general condition.

The usual dose for children over 5 years of age is one 5mg tablet twice a day.

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

These directions may differ from the information contained in this leaflet.

**If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.**

### *How to take it*

Swallow Oxybutynin Sandoz with a glass of water.

### *When to take it*

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

### *How long to take it*

**Continue taking the tablets for as long as your doctor or pharmacist tells you.**

Oxybutynin Sandoz helps control your condition, but does not cure it. Therefore, you must take Oxybutynin Sandoz every day.

### *If you forget to take it*

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 it as soon as you remember, and continue to take it as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

### *If you take too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Oxybutynin Sandoz. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include:

- restlessness or excitement
- flushing, light headedness or dizziness

- difficulty in breathing
- numbness in the hands or feet.

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## While you are taking Oxybutynin Sandoz

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### *Things you must do*

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Oxybutynin Sandoz.

If you are going to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Oxybutynin Sandoz.

If you become pregnant while taking this medicine, tell your doctor immediately.

### *Things you must not do*

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

**Do not take Oxybutynin Sandoz to treat any other complaints unless your doctor or pharmacist tells you to.**

### *Things to be careful of*

**Oxybutynin Sandoz may make you sweat less, causing your body temperature to rise. Take extra care to avoid becoming overheated during exercise or hot weather, since overheating may result in heat stroke.**

This is particularly relevant to children who often run around playing in the hot sun.

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

This medicine may cause drowsiness or blurred vision in some people. If you have any of these symptoms, do not drive a car, operate machinery, or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking this medicine.**

Alcohol or other sedatives may increase the drowsiness that may be caused by Oxybutynin Sandoz.

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## Side effects

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All medicines can have side effects. 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.

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

Oxybutynin Sandoz helps most people, but it may have unwanted side effects in a few people. If you are elderly, you may be especially sensitive to the effects of Oxybutynin Sandoz. This may increase the chance of side effects during treatment.

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

- nausea or vomiting
- headache
- dryness of the mouth, nose and throat
- drowsiness
- constipation
- decreased sweating
- diarrhoea
- stomach discomfort
- loss of appetite
- heartburn
- dry skin.

These side effects are usually mild.

**Tell your doctor or pharmacist immediately if you notice any of the following:**

- fast or irregular heartbeat
- flushing
- dizziness

- unusual tiredness or weakness
- restlessness or trouble sleeping
- hallucinations
- nightmares
- confusion, nervousness (feeling anxious) or severe suspiciousness (paranoia)
- agitation
- convulsions, fits or seizures
- eye problems, including dry eyes or blurred vision
- difficulty urinating
- skin rash
- decreased flow of breast milk
- impotence.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:**

- fever or heat stroke
- numbness in the hands or feet.
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- hives
- fainting
- yellowing of the skin and eyes also called jaundice

These are very serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

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

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

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## After taking it

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### *Storage*

**Keep your tablets in the bottle until it is time to take them.**

If you take the tablets out of the bottle they will not keep well.

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

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

**Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

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

### *Disposal*

If your doctor or pharmacist tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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## Product description

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### *What it looks like*

Oxybutynin Sandoz 5mg tablets - light blue, round, single scored tablets, blank on both sides.

Available in bottles containing 100 tablets.

### *Ingredients*

Oxybutynin Sandoz does not contain gluten, sucrose, tartrazine or any other azo dyes.

Active ingredient:

- Oxybutynin Sandoz 5mg - 5mg oxybutynin hydrochloride

Inactive ingredients:

- lactose anhydrous
- microcrystalline cellulose
- calcium stearate

- Brilliant Blue FCF (CI 42090).

### *Distributor*

Sandoz Pty Ltd  
ABN 60 075 449 553  
54 Waterloo Road  
Macquarie Park, NSW 2113  
Australia  
Tel: 1800 634 500

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