

Fluconazole Sandoz®

fluconazole capsules

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Fluconazole 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 want to read it again.

WHAT FLUCONAZOLE SANDOZ IS USED FOR

This medicine is used to treat certain types of fungal or yeast infections.

It contains the active ingredient fluconazole.

Fluconazole belongs to a group of medicines called azole antibiotics.

It works by preventing the growth of the fungal and yeast organisms causing your infection.

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.

This medicine is not addictive.

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

BEFORE YOU TAKE FLUCONAZOLE SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- fluconazole, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under PRODUCT DESCRIPTION
- any other similar antifungal medicines such as miconazole, ketoconazole or clotrimazole.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are taking:

- cisapride, a medicine used to treat stomach problems
- terfenadine, a medicine used to treat allergies, and you are taking Fluconazole Sandoz at a dose of 400mg a day or higher.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or 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 if you have allergies to any other medicines, foods, preservatives or dyes.

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

- kidney problems
- liver problems
- heart problems.

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.

If you have not told your doctor about any of the above, tell him/her before you start taking Fluconazole 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 and Fluconazole Sandoz may interfere with each other. These include:

- terfenadine and astemizole, medicines used to control allergies
- cisapride, a medicine used to treat stomach problems
- warfarin, a medicine used to stop blood clots
- phenytoin or carbamazepine, medicines used to control epilepsy

- theophylline, a medicine used to treat asthma
- medicines used for sedation, such as midazolam
- hydrochlorothiazide, used for treating fluid problems or to treat high blood pressure
- birth control pills
- medicines used to control the immune system such as cyclosporin, tacrolimus, everolimus, tofacitinib, prednisone or sirolimus.
- some antiviral and antibiotic medicines such as rifampicin, rifabutin, zidovudine, amphotericin B, voriconazole or erythromycin
- some medicines used to treat diabetes such as glipizide, tolbutamide and glibenclamide
- cyclophosphamide, a medicine used to treat some cancers
- NSAIDs such as naproxen, diclofenac and celecoxib
- opioid pain killers such as alfentanil, fentanyl and methadone
- losartan, a medicine used to treat high blood pressure
- calcium channel blockers, medicines used to treat high blood pressure and angina
- cholesterol-lowering medicines, such as atorvastatin, fluvastatin or simvastatin
- amiodarone and quinidine, medicines used to treat abnormal or irregular heartbeat
- pimozide, an antipsychotic medicine, used to treat mental illness
- halofantrine, a medicine used to treat malaria
- antidepressants such as amitriptyline and nortriptyline.

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

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

HOW TO TAKE FLUCONAZOLE SANDOZ

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

They may differ from the information contained in this leaflet.

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

How much to take

Adults

The dose will depend on your infection and how you respond to this medicine. It usually ranges from 50mg to 400mg once daily.

Children

The dose for a child will depend on body weight and usually ranges from 3mg to 12mg per kilogram of body weight.

However, depending on how serious the infection is, and how you react to this medicine, your doctor may ask you to take a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Fluconazole Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the capsules whole with a full glass of water.

When to take Fluconazole Sandoz

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.

It does not matter if you take this medicine before or after food.

How long to take Fluconazole Sandoz

Continue taking your medicine for as long as your doctor tells you.

The length of time you take this medicine will depend on the sort of infection you have. Patients with a weakened immune system or those with difficult infections may need long term treatment to prevent the infection from returning.

Do not stop taking your medicine because you are feeling better.

If you do not complete the full course prescribed by your doctor, the infection may not completely clear or your symptoms may return.

If you forget to take it

Take your dose as soon as you remember, and continue to take it 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.

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 when 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 Australia 13 11

26 or New Zealand 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Fluconazole Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING FLUCONAZOLE SANDOZ

Things you must do

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

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

If you are a woman of childbearing age, you should avoid becoming pregnant while taking Fluconazole Sandoz.

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

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

Things you must not do

Do not take Fluconazole Sandoz to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you do not complete the full course prescribed by your doctor, all of the organisms causing your infection may not be killed. These organisms may continue to grow and multiply so that your infection

may not clear completely or may return.

Things to be careful of

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

This medicine may cause dizziness or seizures occasionally in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be sure to follow your doctor's advice if regular checks on your liver are recommended.

In rare cases, Fluconazole Sandoz may affect the liver and may need to be stopped.

If you suffer from HIV or have a weakened immune system and develop a rash while taking this medicine, tell your doctor immediately.

If this rash worsens, this medicine may need to be stopped.

SIDE EFFECTS

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

This medicine helps most people with fungal and yeast infections, but it may have a few unwanted effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- acne
- nausea or feeling sick, vomiting

- stomach pain, indigestion, diarrhoea
- headache.

These are mild side effects of the medicine, and are short-lived.

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

- sudden or severe itching, skin rash, hives
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- flaking of the skin
- yellowing of the skin or eyes, also called jaundice
- increased sweating
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

- symptoms of a hypersensitivity reaction such as swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- asthma, wheezing, allergic reactions which can cause shortness of breath or difficulties breathing
- fainting, fits or seizures
- fast or irregular heartbeat.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

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

AFTER TAKING FLUCONAZOLE SANDOZ

Storage

Keep your medicine in the original packaging.

If you take it out of its original container it may not keep well.

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

Do not store Fluconazole 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 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.

PRODUCT DESCRIPTION

What it looks like

Fluconazole Sandoz comes in three types of capsules:

Fluconazole Sandoz 50mg - Hard gelatin capsules with a turquoise cap and white body, marked with FC50.

Fluconazole Sandoz 100mg - Hard gelatin capsules with a blue cap and white body, marked with FC100.

Fluconazole Sandoz 200mg - Hard gelatin capsules with a purple cap and white body, marked with FC200.

Available in blister packs of 28 capsules.

Ingredients

Active ingredient:

- Fluconazole Sandoz 50mg - 50mg fluconazole.
- Fluconazole Sandoz 100mg - 100mg fluconazole.
- Fluconazole Sandoz 200mg - 200mg fluconazole.

Inactive ingredients:

- lactose
- maize starch
- magnesium stearate
- colloidal anhydrous silica
- sodium lauryl sulfate
- titanium dioxide
- gelatin
- indigo carmine CI73015
- brilliant scarlet 4R CI16255 (200mg capsules only)
- shellac
- black monogramming ink (107581 or 2328)
- propylene glycol.

Supplier

Sandoz Pty Ltd
54 Waterloo Road
Macquarie Park
NSW 2113
Australia
Tel: 1800 634 500

Novartis New Zealand Ltd
PO Box 99102
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New Zealand
Tel: 0800 354 335

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Australian Register Numbers

50mg capsules: AUST R 104285 (blisters)

100mg capsules: AUST R 104288 (blisters)

200mg capsules: AUST R 104293 (blisters)