

Fluconazole Sandoz®

fluconazole injection

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Fluconazole Sandoz injection.

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 having this medicine against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

WHAT FLUCONAZOLE SANDOZ IS USED FOR

This medicine is used to treat certain fungal and 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 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 ARE GIVEN FLUCONAZOLE SANDOZ

When it must not be given

This medicine should not be given 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 medicines related to fluconazole 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 have this medicine if you are receiving doses of 400mg or more of Fluconazole Sandoz per day, and you are taking terfenadine (a medicine used to treat allergies).

Do not have this medicine if you are taking cisapride (a medicine used to treat stomach problems).

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

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- liver problems
- heart problems
- kidney 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 are given Fluconazole Sandoz injection.

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 Fluconazole Sandoz may interfere with each other. These include:

- some medicines used to treat allergies, such as astemizole and terfenadine
- some medicines for diabetes such as glipizide, tolbutamide or glibenclamide
- some antibiotics and antiviral drugs such as rifampicin, rifabutin, zidovudine, amphotericin B or erythromycin

- some medicines used in problems with the immune system, such as cyclosporin, tacrolimus, everolimus, prednisone or sirolimus
- warfarin (used to stop blood clots)
- phenytoin (used to treat epilepsy)
- theophylline (used to treat asthma)
- some benzodiazepines such as midazolam
- hydrochlorothiazide (used for treating fluid problems)
- the contraceptive pill (birth control pill)
- carbamazepine (used in the treatment of epilepsy and bipolar disorder)
- cisapride (used to treat stomach problems)
- 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
- quinidine, a medicine used to treat abnormal or irregular heart beat
- pimozone, 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 having this medicine.

HOW FLUCONAZOLE SANDOZ IS GIVEN

Fluconazole Sandoz injection can only be given by a doctor or nurse. It is usually infused slowly into a vein.

How much to have

The amount of Fluconazole Sandoz injection you receive and the length of your treatment will depend on your body weight and kidney function. It will also depend on how quickly the infection is brought under control.

After a while, the injection may be stopped and you may begin to receive fluconazole capsules by mouth.

If you are given too much (overdose)

Because Fluconazole Sandoz injection is given to you by a health professional, overdose is unlikely to arise. However, you should tell your doctor or nurse immediately if you feel unwell while you are receiving this medicine.

WHILE YOU ARE GIVEN 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 receiving Fluconazole Sandoz injection.

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

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

If this rash worsens, Fluconazole Sandoz injection 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 receiving Fluconazole Sandoz injection.

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:

- nausea or feeling sick, vomiting
- dry mouth, thirst
- headache
- stomach pain, indigestion, diarrhoea
- acne.

These are the more common side effects of this medicine. They are usually mild and short-lived.

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

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives

- fainting, seizures or fits
- flaking of the skin
- yellowing of the skin or eyes, also called jaundice
- increased sweating
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- fast or irregular heartbeat.

These side effects are usually rare but can be serious and need urgent medical attention.

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 HAVING FLUCONAZOLE SANDOZ

Storage

Fluconazole Sandoz injection is stored by the hospital pharmacy, and should be kept in the original packaging until immediately before use.

It should be kept in a cool dry place where the temperature stays below 25°C. It should not be refrigerated or frozen.

PRODUCT DESCRIPTION

What it looks like

Fluconazole Sandoz injection comes in two strengths:

- Fluconazole Sandoz 100mg/50mL - clear, colourless solution, free from visible particles.

- Fluconazole Sandoz 200mg/100mL - clear, colourless solution, free from visible particles.

Available in packs containing 1 vial.

Ingredients

Active ingredients:

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

Inactive ingredients:

- sodium chloride
- hydrochloric acid
- water for injections.

Supplier

Fluconazole Sandoz injection is supplied in Australia by:

Sandoz Pty Ltd

ABN 60 075 449 553
19 Harris Street
Pymont NSW 2009
Australia
Tel: 1800 634 500

Novartis New Zealand Ltd

Private Bag 65904 Mairangi Bay
Auckland 0754
New Zealand
Tel: 0800 354 335

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Australian Register Numbers

100mg/50mL injection: AUST R 104301

200mg/100mL injection: AUST R 104302