

Fluconazole Winthrop®

Fluconazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fluconazole Winthrop. 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 risk of you taking Fluconazole Winthrop against the benefits it is expected to 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 Winthrop is used for

The name of your medicine is Fluconazole Winthrop. It contains the active ingredient fluconazole. Fluconazole Winthrop is used to treat certain types of fungal or yeast infection. Your doctor may have prescribed Fluconazole Winthrop for another reason.

Ask your doctor if you have any questions about why Fluconazole Winthrop was prescribed for you.

How Fluconazole Winthrop works

Fluconazole Winthrop belongs to a group of medicines called bis-triazole antibiotics.

It works by stopping the growth of organisms (fungus or yeast) which cause infections.

There is no evidence that Fluconazole Winthrop is addictive.

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

Before you take Fluconazole Winthrop

When you must not take Fluconazole Winthrop

Do not take Fluconazole Winthrop if:

- You are allergic to the active ingredient or any of the inactive ingredients mentioned at the end of this leaflet under Product Description.
- It is past its expiry date or the packaging appears to have been tampered with.
- You are pregnant or breastfeeding, unless permitted by your doctor.
- You are taking cisapride, a medicine used to treat stomach problems.
- You are taking terfenadine, a medicine used to treat allergies, the dose of Fluconazole Winthrop should not exceed 400mg a day.
- You are taking doses of 400mg or more a day of Fluconazole or related azole compounds.

Before you start to take Fluconazole Winthrop

Tell your doctor if you have allergies to:

- Any other medicines, especially if they are in the same drug class as fluconazole.

- Any other substances, including foods, preservatives or dyes.

Tell your doctor if you plan on becoming pregnant or will be breastfeeding while you are using Fluconazole Winthrop.

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

- Kidney problems.
- Liver problems.
- Heart problems.

Taking other medicines

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

In particular, tell your doctor if you take any of the following:

- Terfenadine and astemizole, medicines used to control allergies.
- Cisapride, a medicine used to treat stomach problems.
- Warfarin, a medicine used to thin the blood.
- Phenytoin, a medicine used to control epilepsy.
- Theophylline, a medicine used to treat asthma.
- Medicines used for sedation, such as midazolam.
- Hydrochlorothiazide, used as a fluid tablet or to treat high blood pressure.
- Birth control pills.
- Medicines used to control the immune system such as

cyclosporine, tacrolimus or sirolimus.

- Some antiviral and antibiotic medicines including rifampicin, rifabutin, zidovudine, amphotericin B or erythromycin.
- 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.
- Antidepressants such as amitriptyline and nortriptyline.

These medicines may be affected by Fluconazole Winthrop, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

How to take FLUCONAZOLE WINTHROP

Always follow the directions given to you by your doctor or pharmacist carefully.

They might differ from the information contained in this leaflet. If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

Adults:

How much and how often Fluconazole Winthrop needs to be taken depends on your infection.

The dose is usually between 50mg to 400mg once daily.

Children:

The dose varies with body weight and is usually between 3mg to 12 mg per kilogram of body weight.

Fluconazole Winthrop capsules should be swallowed whole with a glass of water. It can be taken before, with or after food and should be taken at the same time each day.

Continue taking Fluconazole Winthrop until you finish your pack or as directed by your doctor.

If you forget to take your dose

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.

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

Immediately telephone your doctor, or the Poisons Information Centre (telephone 131 126) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Fluconazole Winthrop.

Do this even if there are no signs of discomfort or poisoning.

While you are using FLUCONAZOLE WINTHROP

Things you must do

- **Always follow your doctor's instructions carefully.**
- **Tell your doctor if you become pregnant while taking Fluconazole Winthrop.**
- **Tell your doctor if symptoms of your infection do not improve within a few days.**

- **If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Fluconazole Winthrop.**

Things you must not do

- Do not stop taking Fluconazole Winthrop without your doctor's permission.
- Do not use Fluconazole Winthrop to treat any other complaint unless your doctor says so.
- Do not give this medication to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful driving or operating machinery until you know how Fluconazole Winthrop affects you. Fluconazole Winthrop may cause dizziness or seizures occasionally in some people.

Side effects

All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

- Acne.
- Nausea, vomiting.
- Stomach cramp, diarrhoea.
- Headache.

These are the more common side effects of Fluconazole Winthrop. Mostly, these are mild and short-lived. Fluconazole is generally well tolerated.

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

- Skin reactions/ rash.
- Bleeding or bruising more easily than normal.
- Flaking of the skin.

- Yellowing of the skin or eye, which may indicate hepatitis.
- Increased sweating.
- Worsening of your infection, with symptoms such as fever, severe chills.

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

If any of the following happen, stop taking Fluconazole Winthrop and 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.
- Allergic reactions which can cause shortness of breath or difficulties breathing.
- Fits or seizures.
- Fast or irregular heartbeat.

These are very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

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

Tell your doctor if you notice any other effects.

After using FLUCONAZOLE WINTHROP

Storage

Keep Fluconazole Winthrop in the original packaging until you need to take it.

Store below 25 degrees C in a dry place, out of the reach of children.

Disposal

Return any unused or out of date medicine to your pharmacist.

Product description

What Fluconazole Winthrop looks like

Fluconazole Winthrop 100mg capsules: Hard gelatin capsules, blue cap white body with the imprint FC100. Available in blister packs of 28 capsules.

Fluconazole Winthrop 200mg capsules: Hard gelatin capsules, purple cap white body with the imprint FC200. Available in blister packs of 28 capsules.

Ingredients

Active Ingredient

Each Fluconazole Winthrop 100mg capsule contains 100mg fluconazole.

Each Fluconazole Winthrop 200mg capsule contains 200mg fluconazole.

Inactive Ingredients

As well as the active ingredient, fluconazole, Fluconazole Winthrop also contains some inactive ingredients. These are lactose monohydrate, starch-maize, magnesium stearate, silica- colloidal anhydrous, sodium lauryl sulfate, titanium dioxide, gelatin, Indigo Carmine C173015 and Brilliant Scarlet 4R CI16255 (200mg capsules only). Printing Ink: Shellac, iron oxide- black, lecithin, antifoam DC 1510.

Supplier

Fluconazole Winthrop is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road,

Macquarie Park, NSW 2113

Freecall No: 1800 818 806

Fluconazole Winthrop is supplied in New Zealand by:

sanofi-aventis new zealand limited

Auckland, New Zealand

Freecall No: 0800 283 684

This leaflet was prepared in September 2010.

Australian Register Numbers

Fluconazole 100mg capsules: AUST R 132654

Fluconazole 200mg capsules: AUST R 132656

#82108v2