

Chemists' Own Femazole One

Fluconazole 150 mg capsule

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CHEMISTS' OWN FEMAZOLE ONE.

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

All medicines have benefits and risks. Your doctor or pharmacist has weighed the risks of you using CHEMISTS' OWN FEMAZOLE ONE against the benefits expected for you.

If you have any concerns about using this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

This information in this leaflet relates only to CHEMISTS' OWN FEMAZOLE ONE. It is not to be used in relation to any other product, which may contain the same active ingredient.

What CHEMISTS' OWN FEMAZOLE ONE is used for

CHEMISTS' OWN FEMAZOLE ONE is used to treat a fungal infection known as vaginal thrush.

The active ingredient in CHEMISTS' OWN FEMAZOLE ONE is fluconazole, which is classified with medicines known as azole antifungals. This group of antifungal medicines work by preventing the growth of fungi causing your infection.

Ask your doctor or pharmacist if you have any questions about why CHEMISTS' OWN FEMAZOLE ONE has been recommended for you.

Your doctor or pharmacist may have recommended CHEMISTS' OWN FEMAZOLE ONE for another reason.

CHEMISTS' OWN FEMAZOLE ONE is not recommended for children under 18 years of age except under doctor supervision.

There is no evidence that either component in CHEMISTS' OWN FEMAZOLE ONE is addictive.

CHEMISTS' OWN FEMAZOLE ONE is a "Pharmacist Only Medicine". It is available without a doctor's prescription, but your pharmacist's advice is required.

What is vaginal thrush

Vaginal candidiasis, and infection caused by a yeast-like fungus *Candida*, is commonly referred to as "vaginal thrush".

Candida is one of many organisms that live in the vagina and its growth is normally balanced by your body's natural defence mechanism known as the 'immune system'. However, when this natural balancing is upset, *Candida* can multiply in the vagina to cause the symptoms of thrush.

Common symptoms of vaginal thrush include:

- itching, burning or soreness around the vagina
- cottage-cheese like discharge
- swelling or irritation of the infected area.

What you can do to avoid thrush in the future:

- avoid wearing synthetic clothing
- wear loose-fitting cotton briefs, stockings
- wash the area regularly, but not wash and dry yourself harshly
- avoid vaginal deodorants, perfumed soaps and bath additives

Ask your doctor or pharmacist for more information on things you can do to avoid thrush in the future.

Before you take CHEMISTS' OWN FEMAZOLE ONE

When you must not take it

Do not take CHEMISTS' OWN FEMAZOLE ONE if you have an allergy to:

- medicines containing fluconazole
- medicines related to fluconazole such as miconazole (eg. Daktarin), ketoconazole (eg. Nizoral) or clotrimazole (eg. Canestan, Clonea), itraconazole (Sporanox)
- 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, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

- Do not take CHEMISTS' OWN FEMAZOLE ONE if**

you are taking cisapride (Prepulsid), a medicine used to treat stomach problems.

- Astemizole
- Pimozide
- quinidine

Combining CHEMISTS' OWN FEMAZOLE ONE with cisapride may cause serious side effects such as an abnormal heart rhythm.

Do not take CHEMISTS' OWN FEMAZOLE ONE if you are pregnant, suspect you may be pregnant or if you may become pregnant during treatment.

CHEMISTS' OWN FEMAZOLE ONE should not be used during pregnancy as it may affect your developing baby.

Do not take CHEMISTS' OWN FEMAZOLE ONE if you are breastfeeding.

CHEMISTS' OWN FEMAZOLE ONE passes into breast milk and may affect your baby.

Do not take CHEMISTS' OWN FEMAZOLE ONE if the expiry date (EXP) printed on the packaging has passed.

Do not take CHEMISTS' OWN FEMAZOLE ONE if the packaging shows signs of tampering or the capsule does not look quite right.

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

Before you start to use it

Tell your doctor or pharmacist if you are allergic to any other medicines, foods, dyes or preservatives.

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

- thrush more than twice in the last six months
- any liver problems
- any kidney problems
- any heart problems
- diabetes
- HIV infection or AIDS

Your doctor or pharmacist may want to take special care if you have any of these conditions.

Tell your doctor or pharmacist before using CHEMISTS' OWN FEMAZOLE ONE if you are taking warfarin (eg. Marevan, Coumadin) as bleeding or bruising may occur.

Tell your doctor or pharmacist if you are experiencing any of the following:

- abdominal or irregular vaginal bleeding or blood-stained discharge
- Foul smelling or unusual coloured discharge
- Vulval or vaginal sores, ulcers or blisters
- Lower abdominal pain or burning when passing urine
- Fever or chills.

If you have not told your doctor about any of the above, tell them before you start taking CHEMISTS' OWN FEMAZOLE ONE.

Taking other medicines

Do not take CHEMISTS' OWN FEMAZOLE ONE if you are taking:

- cisapride (Prepulsid), a medicine used to treat stomach problems
- astemizole
- pimozide
- quinidine.

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

Some medicines and CHEMISTS' OWN FEMAZOLE ONE may interfere with each other. These include:

- warfarin (eg. Marevan, Coumadin), a medicine used to prevent blood clots
- phenytoin (eg. Dilantin) or carbamazepine (eg. Tegretol), medicines used to treat epilepsy

- cyclosporin (eg. Neoral), sirolimus (eg. Rapamune) or tacrolimus (eg. Prograf), medicines used to prevent organ transplant rejection or to treat certain problems with the immune system
- certain medicines use to treat diabetes such as:
 - glibenclamide (eg. Daonil, Glimel), glipizide (eg. Minidiab, Melizide), glimepiride (eg. Amaryl), gliclazide (eg. Diamicon, Glyade)
 - pioglitazone (eg. Actos), rosiglitazone (eg. Avandia)
- rifampicin (eg. Rifadin, Rimycin) or rifabutin (eg. Mycobutin), antibiotics used to treat infections
- theophylline (eg. Nuelin), a medicine used to treat asthma
- midazolam (eg. Hypnovel) and triazolam (eg. Halcion), medicines used as sedatives or to treat anxiety
- zidovudine (eg. Retrovir), saquinavir (eg. Invirase), medicines used to treat AIDS patients
- hydrochlorothiazide (eg. Dithiazide), a medicine used for treating fluid problems and high blood pressure
- the contraceptive pill (birth control pill)
- amphotericin B (eg. Fungilin), a medicine used to treat fungal infection
- erythromycin (eg. E-Mycin) and azithromycin (eg. Zithromax), antibiotics used to treat certain types of bacterial infections
- anticancer drugs such as cyclophosphamide, vincristine and vinblastine, medicines used to treat certain types of cancers
- carbamazepine (eg. Tegretol), a medicine used in the treatment of epilepsy and bipolar disorder
- NSAIDs such as naproxen, diclofenac and celecoxib (eg. Celebrex)

- opioid pain killers such as alfentanil, fentanyl and methadone
- losartan, a medicine used to treat high blood pressure
- calcium channel blockers, such as nifedipine, amlodipine and felodipine used in relieving high blood pressure and certain heart conditions
- statins such as atorvastatin, simvastatin and fluvastatin, used to control high cholesterol levels
- antidepressants such as amitriptyline (eg. Endep) and nortriptyline.

Talk to your doctor about the need for an additional method of contraception while taking CHEMISTS' OWN FEMAZOLE ONE.

It may decrease the effectiveness of some birth control pills.

Your doctor can tell you what to do if you are taking any of these medicines.

These medicines may be affected by CHEMISTS' OWN FEMAZOLE ONE 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 Chemists' Own FEMAZOLE ONE.

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

They may 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.

How much to take

Adults

For vaginal thrush in adults, only a single dose (1 capsule) of CHEMISTS' OWN FEMAZOLE ONE is needed.

CHEMISTS' OWN FEMAZOLE ONE is not recommended for children under 18 years of age except under doctor supervision.

How to take it

Swallow the capsule whole with a glass of water.

When to take it

CHEMISTS' OWN FEMAZOLE ONE can be taken any time before, with or after food.

If you take too much CHEMISTS' OWN FEMAZOLE ONE (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26 IN Australia or 0800 764 766 in New Zealand) or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have used too much CHEMISTS' OWN FEMAZOLE ONE.

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

You may need urgent medical attention.

CHEMISTS' OWN FEMAZOLE ONE.

- **Use effective contraception to prevent pregnancy while taking CHEMISTS' OWN FEMAZOLE ONE.**
- **Immediately tell your doctor if you do become pregnant while taking CHEMISTS' OWN FEMAZOLE ONE.**
- **If your symptoms of your infection do not improve after 3 days, or if they become worse, tell your doctor or pharmacist.**

Things you must not do

- **Do not use CHEMISTS' OWN FEMAZOLE ONE to treat any other medical complaints unless your doctor or pharmacist tells you to.**
- **Do not give CHEMISTS' OWN FEMAZOLE ONE to anyone else, even if they have the same condition as you.**

Things to be careful of

- **Tell your doctor immediately if you develop a rash while taking CHEMISTS' OWN FEMAZOLE ONE**
- People with AIDS or a weak immune system may be more prone to serious side effects of the skin.

While you are taking CHEMISTS' OWN FEMAZOLE ONE

Things you must do

- **Before starting any new medicine, tell your doctor or pharmacist that you are taking or have taken CHEMISTS' OWN FEMAZOLE ONE.**
- **Tell any other doctors, dentists and pharmacists who treat you that you are taking**

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CHEMISTS' OWN FEMAZOLE ONE.

This medicine helps most people and is generally well tolerated. However it may have unwanted side 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 treatment if you get some of the side effects.

Do not be alarmed by the following list of possible 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 (feeling sick), vomiting
- stomach pain, indigestion
- diarrhoea
- acne
- headache.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- unusual muscle stiffness causing poor control of movement
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers 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
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- passing more urine than normal, kidney pain (pain on the sides of the body)
- symptoms of liver disease such as yellowing of the skin or eyes; dark urine, pale stools; loss of appetite; unusual tiredness
- irregular heart beat or palpitations
- increased sweating.

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

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 that is making you feel unwell.

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

After taking CHEMISTS' OWN FEMAZOLE ONE

Storage

Keep CHEMISTS' OWN FEMAZOLE ONE where young children cannot reach it.

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

Keep your medicine in its original pack until it is time to take it.

If you take it out of the pack it may not keep well.

Keep CHEMISTS' OWN FEMAZOLE ONE capsules in a cool, dry place where the temperature stays below 25°C.

Do not store CHEMISTS' OWN FEMAZOLE ONE in the bathroom or near a sink

Do not leave CHEMISTS' OWN FEMAZOLE ONE on a window sill or in the car.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

CHEMISTS' OWN FEMAZOLE ONE capsule is a hard gelatin capsule with sky blue opaque body and cap.

Each pack contains 1 capsule.

Ingredients

The active ingredient in the CHEMISTS' OWN FEMAZOLE ONE is fluconazole 150 mg/capsule.

Each capsule also contains the following inactive ingredients:

lactose monohydrate
starch maize
gelatin
silica colloidal anhydrous
sodium lauryl sulfate
titanium dioxide
talc purified
patent blue V

This medicine contains sugars (as lactose) and sulfites.

Supplier:

CHEMISTS' OWN FEMAZOLE ONE is supplied in Australia by:

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street,
Cremorne, VIC 3121
Web: www.arrotex.com.au

Australian Registration Number:
AUST R 299349

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