

## CONSUMER MEDICINE INFORMATION

**generic**health

### PHARMACY ACTION FEMRELIEF ONE

Fluconazole 150 mg capsule

#### What is in this leaflet

This leaflet answers some common questions about PHARMACY ACTION FEMRELIEF 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 PHARMACY ACTION FEMRELIEF 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 PHARMACY ACTION FEMRELIEF ONE. It is not to be used in relation to any other product, which may contain the same active ingredient.

#### What PHARMACY ACTION FEMRELIEF ONE is used for

PHARMACY ACTION FEMRELIEF ONE is used to treat a fungal infection known as vaginal thrush.

The active ingredient in PHARMACY ACTION FEMRELIEF 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 PHARMACY ACTION FEMRELIEF ONE has been recommended for you.

Your doctor or pharmacist may have recommended PHARMACY ACTION FEMRELIEF ONE for another reason.

PHARMACY ACTION FEMRELIEF ONE is not recommended for children under 18 years of age except under doctor supervision.

There is no evidence that either component in PHARMACY ACTION FEMRELIEF ONE is addictive.

PHARMACY ACTION FEMRELIEF 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 balance 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 use PHARMACY ACTION FEMRELIEF ONE

##### When you must not take it

Do not take PHARMACY ACTION FEMRELIEF 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 PHARMACY ACTION FEMRELIEF ONE if you are taking cisapride (Prepulsid), a medicine used to treat stomach problems.**

Combining PHARMACY ACTION FEMRELIEF ONE with cisapride may cause serious side effects such as an abnormal heart rhythm.

**Do not take PHARMACY ACTION FEMRELIEF ONE if you are pregnant, suspect you may be pregnant or if you may become pregnant during treatment.**

PHARMACY ACTION FEMRELIEF ONE should not be used during pregnancy as it may affect your developing baby.

**Do not take PHARMACY ACTION FEMRELIEF ONE if you are breastfeeding.** PHARMACY ACTION FEMRELIEF ONE passes into breast milk and may affect your baby.

**Do not take PHARMACY ACTION FEMRELIEF ONE if the expiry date (EXP) printed on the packaging has passed.**

**Do not take PHARMACY ACTION FEMRELIEF 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:

- abdominal or irregular vaginal bleeding or blood stained discharge;
- vulvar or vaginal sores, ulcers or blisters;
- lower abdominal pain or burning when passing urine;
- any liver problems;
- any kidney problems;
- any heart problems.

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

**Tell your doctor or pharmacist before using PHARMACY ACTION FEMRELIEF ONE if you are taking warfarin (eg. Marevan, Coumadin) as bleeding or bruising may occur.**

**If you have not told your doctor about any of the above, tell them before you start taking PHARMACY ACTION FEMRELIEF ONE.**

### ***Taking other medicines***

**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.**

**If you are taking cisapride (Prepulsid), a medicine used to treat stomach problems, do not take PHARMACY ACTION FEMRELIEF ONE.**

Some medicines and PHARMACY ACTION FEMRELIEF ONE may interfere with each other. These include:

- Some medicines to treat diabetes, such as glipizide (eg. Minidiab, Melizide), tolbutamide or glibenclamide (eg. Daonil, Glimel), glimepiride (eg. Amaryl), gliclazide (eg. Diamicon, Glyade), pioglitazone (eg. Actos), or rosiglitazone (eg. Avandia).
- Some antibiotics and antiviral drugs, such as rifampicin (eg. Rifadin, Rimycin), rifbutin (Mycobutin) or zidovudine.
- Some drugs used in problems with the immune system, such as cyclosporine or tacrolimus.
- Warfarin (used to stop blood clots).
- Phenytoin (used to treat epilepsy).
- Theophylline (used to treat asthma).

- Some benzodiazepines such as midazolam (eg. Hypnovel) and triazolam (eg. Halcion).
- Hydrochlorothiazide (Dithaizide) used for treating fluid problems and high blood pressure.
- The contraceptive pill (birth control pill).

**Talk to your doctor about the need for an additional method of contraception while using PHARMACY ACTION FEMRELIEF ONE.**

PHARMACY ACTION FEMRELIEF ONE may decrease the effectiveness of some birth control pills.

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

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

These medicines may be affected by PHARMACY ACTION FEMRELIEF ONE or may affect how well PHARMACY ACTION FEMRELIEF ONE or these medicines work. 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 PHARMACY ACTION FEMRELIEF ONE.

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### **How to take PHARMACY ACTION FEMRELIEF ONE**

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**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 PHARMACY ACTION FEMRELIEF ONE is needed.

**PHARMACY ACTION FEMRELIEF 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***

PHARMACY ACTION FEMRELIEF ONE can be taken any time before, with or after food.

### ***If you take too much PHARMACY ACTION FEMRELIEF 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 PHARMACY ACTION FEMRELIEF ONE.

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

You may need urgent medical attention.

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## **While you are taking PHARMACY ACTION FEMRELIEF ONE**

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### ***Things you must do***

**Before starting any new medicine, tell your doctor or pharmacist that you are taking or have taken PHARMACY ACTION FEMRELIEF ONE.**

**Tell any other doctors, dentists and pharmacists who treat you that you are taking PHARMACY ACTION FEMRELIEF ONE.**

**Use effective contraception to prevent pregnancy while taking PHARMACY ACTION FEMRELIEF ONE.**

**Immediately tell your doctor if you do become pregnant while taking PHARMACY ACTION FEMRELIEF 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 PHARMACY ACTION FEMRELIEF ONE to treat any other medical complaints unless your doctor or pharmacist tells you to.**

**Do not give PHARMACY ACTION FEMRELIEF 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 PHARMACY ACTION FEMRELIEF ONE.**

People with AIDS or a weak immune system may be more prone to serious side effects of the skin.

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## **Side effects**

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

PHARMACY ACTION FEMRELIEF ONE helps most people with 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 treatment if you get some of the side effects.

**Do not be alarmed by the following list 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 'feeling sick', vomiting;
- stomach pain, indigestion;
- Diarrhoea;
- 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;
- frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- bleeding or bruising more easily than normal;
- 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 -also called jaundice; dark urine, pale stools; loss of appetite; unusual tiredness;
- an irregular heart beat or palpitations.

These side effects are serious and need medical attention.

**Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:**

- signs of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath;
- severe blisters and bleeding of the lips, eyes, mouth, nose and genitals;
- a severe rash with skin peeling, fever, chills and aching muscles.

These side effects are rare, but very serious and require urgent medical attention or hospitalisation.

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

This is not the complete list of all possible side effects. Others may also occur in some people and there may be some side effects not yet known.

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## **After taking PHARMACY ACTION FEMRELIEF ONE**

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### ***Storage***

**Keep PHARMACY ACTION FEMRELIEF 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 PHARMACY ACTION FEMRELIEF ONE capsules in a cool, dry place where the temperature stays below 30°C.**

**Do not store PHARMACY ACTION FEMRELIEF ONE in the bathroom or near a sink**

**Do not leave PHARMACY ACTION FEMRELIEF 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.

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## **Product description**

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### ***What it looks like***

PHARMACY ACTION FEMRELIEF 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 PHARMACY ACTION FEMRELIEF ONE is fluconazole 150 mg/capsule.

Each capsule also contains the following inactive ingredients:

- lactose monohydrate;
- starch maize;
- gelatin;
- silicon colloidal anhydrous;
- sodium lauryl sulfate;
- titanium dioxide;
- talc purified;
- patent blue V.

### ***Supplier***

PHARMACY ACTION FEMRELIEF ONE is supplied in Australia by:

Generic Health Pty Ltd  
Level 1, 1102 Toorak Road  
CAMBERWELL VIC 3124

Australian Registration Number:  
AUST R 279996

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