

# FEMAZOLE ONE

Contains the active ingredient fluconazole

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## Consumer Medicine Information

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### What is in this leaflet

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Please read this leaflet carefully before you start taking FEMAZOLE ONE capsules.

This leaflet answers some common questions about FEMAZOLE ONE capsules. It does not contain all of 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 expected benefits of you taking FEMAZOLE ONE capsules against the risks this medicine could 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 need to read it again.

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### What FEMAZOLE ONE is used for

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FEMAZOLE ONE is used to treat vaginal thrush, a yeast infection of the vagina.

FEMAZOLE ONE belongs to a group of medicines called azole antibiotics.

When taken by mouth, FEMAZOLE ONE works by preventing the growth of the fungal organisms causing your infection.

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

This medicine is not addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

#### **What is vaginal thrush**

Vaginal thrush is a fungal infection of the vagina caused by the yeast named *Candida albicans*.

When you have vaginal thrush, you may have one or more of these common symptoms:

- vaginal itching
- vaginal soreness
- pain during intercourse
- a white, odourless, discharge from the vagina (like cottage cheese)

Rubbing and scratching can aggravate the soreness and itching. Also, the salt of urine can sting the sore tissue.

*Things that may help you avoid thrush in the future*

**Wear cotton briefs, stockings and loose-fitting clothing rather than tight synthetic clothing.**

**Wash regularly but do not wash and dry yourself harshly.**

**Avoid perfumed soaps, bath additives and vaginal deodorants.**

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### Before you take FEMAZOLE ONE

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*When you must not take it*

**Do not take FEMAZOLE ONE if you are pregnant, suspect you are pregnant or are breastfeeding.**

**Do not take FEMAZOLE ONE if you have an allergy to:**

- any medicine containing fluconazole
- any other similar antifungals such as miconazole, ketoconazole or clotrimazole
- any of the ingredients listed at the end of this leaflet.

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 FEMAZOLE ONE if you are taking cisapride (a medicine used to treat stomach problems).**

**Do not take this medicine if the expiry date (EXP) printed on the packaging has passed 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 take this medicine, talk to your doctor or pharmacist.**

*Before you start to take it*

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

**Tell your doctor or pharmacist if you have any other health problems, including:**

- liver problems
- heart problems
- kidney problems.

**Tell your doctor or pharmacist if you have:**

- had thrush more than twice in the last 6 months.

**Tell your doctor or pharmacist before using FEMAZOLE ONE if you are taking warfarin, as bleeding or bruising may occur.**

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

- abnormal or irregular vaginal bleeding or blood stained discharge
- vulval or vaginal sores, ulcers or blisters
- lower abdominal pain or burning when passing urine.

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking FEMAZOLE ONE.**

### *Taking other medicines*

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

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

- some medicines for diabetes such as glimepiride, gliclazide, glipizide or glibenclamide
- warfarin (used to stop blood clots)
- phenytoin (used to treat epilepsy).

Your doctor and pharmacist will have more information on medicines to be careful with or avoid while taking FEMAZOLE ONE.

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## How to take FEMAZOLE ONE

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**Follow all directions given to you by your pharmacist carefully. If you do not understand the instructions on the box, ask your pharmacist for help.**

FEMAZOLE ONE is not recommended for children.

### *How much to take*

The FEMAZOLE ONE treatment for thrush is one capsule.

### *How to take it*

Swallow the capsule whole with water.

### *When to take it*

FEMAZOLE ONE can be taken at any time of the day.

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

### *If you take too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 for advice on management, if you think that you or anyone else may have taken too much FEMAZOLE 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 FEMAZOLE ONE

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### *Things you must do*

**Tell your doctor if the symptoms of your infection do not improve within 3 days, or if they become worse.**

### *Things you must not do*

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

**Do not use FEMAZOLE ONE to treat any other medical complaints unless your doctor tells you to.**

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel**

### **well after you have taken FEMAZOLE ONE.**

This medicine helps most people with vaginal thrush, but it may have a few unwanted effects in a few 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 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 symptoms and they worry you:**

- nausea or feeling sick
- headache
- stomach pain
- indigestion
- diarrhoea.

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

**If you notice any of the following after taking FEMAZOLE ONE, stop taking it and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing (allergic reactions)
- shortness of breath, difficulty with breathing, wheezing, asthma (allergic reactions)
- sudden or severe itching, skin rash, hives (allergic reactions)
- yellowing of the skin or eyes, also called jaundice.

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

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

This is not a 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 using FEMAZOLE ONE

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### *Storage*

**Keep this medicine 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.

**Keep FEMAZOLE ONE capsule in the blister pack in a cool, dry place where it stays below 25°C.**

**Do not store FEMAZOLE ONE in the bathroom or near a sink.**

**Do not leave FEMAZOLE ONE in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep FEMAZOLE ONE capsule in their pack until time to take.**

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

### *Disposal*

**If this medicine 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*

FEMAZOLE ONE capsule is a blue, opaque hard gelatin capsule.

Each pack contains 1 capsule.

### *Ingredients*

The active ingredient in FEMAZOLE ONE is fluconazole.

Each FEMAZOLE ONE capsule contains 150 mg of fluconazole.

The capsule also contains:

- lactose
- pregelatinised maize starch
- sodium lauryl sulfate
- colloidal anhydrous silica
- magnesium stearate
- purified talc.

The capsule shells contain

- gelatin
- sodium lauryl sulfate
- titanium dioxide (E171)
- brilliant blue FCF (E133).

The capsules do not contain gluten, sucrose, tartrazine or any other azo dyes.

### *Sponsor*

Arrow Pharma Pty Ltd  
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Cremorne Victoria 3121

Australian registration number:  
FEMAZOLE ONE – AUST R  
134317

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