

CHEMISTS' OWN FEMAZOLE DUO

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using this medicine?

CHEMISTS' OWN FEMAZOLE DUO contains two components: Chemists' Own Femazole One is an oral capsule which contains the active ingredient fluconazole. Chemists' Own Femazole Vaginal Cream contains the active ingredient clotrimazole, both ingredients belong to a group of medicines called azole antifungals.

For more information, see Section [1. Why am I using this medicine?](#) in the full CMI.

2. What should I know before I use this medicine?

Do not use if you have ever had an allergic reaction to Fluconazole or clotrimazole or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use this medicine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with this medicine and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use this medicine?

- For vaginal thrush in adults, only a single dose (1 capsule) is needed.
- Swallow the capsule whole with a glass of water. The capsule can be taken with or without food.
- Use the cream on the external irritated area 2-3 times a day to relieve the symptoms for as long as they last, usually not more than 3 days.
- Do not give CHEMISTS' OWN FEMAZOLE DUO to children under 18 years of age except under doctor supervision.

More instructions can be found in Section [4. How do I use this medicine?](#) in the full CMI.

5. What should I know while using this medicine?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using CHEMISTS' OWN FEMAZOLE DUO.• Use effective contraception to prevent pregnancy while using CHEMISTS' OWN FEMAZOLE DUO.• Immediately tell your doctor if you do become pregnant while using CHEMISTS' OWN FEMAZOLE DUO.
Things you should not do	<ul style="list-style-type: none">• Do not use CHEMISTS' OWN FEMAZOLE DUO to treat any other conditions unless your doctor or pharmacist tells you to.• Do not give CHEMISTS' OWN FEMAZOLE DUO to anyone else, even if they have the same condition as you.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

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

CHEMISTS' OWN FEMAZOLE DUO helps most people and is generally well tolerated. However, it may have unwanted side effects in some people.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

CHEMISTS' OWN FEMAZOLE DUO

Active ingredient(s): *Fluconazole & Clotrimazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using this medicine. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using this medicine.**

Where to find information in this leaflet:

- [1. Why am I using this medicine?](#)
- [2. What should I know before I use this medicine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use this medicine?](#)
- [5. What should I know while using this medicine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using this medicine?

CHEMISTS' OWN FEMAZOLE DUO is used to treat a type of fungal infection called vaginal thrush.

If this is the first time you have had these symptoms, talk to your doctor before using any treatment.

CHEMISTS' OWN FEMAZOLE DUO contains two components: Chemists' Own Femazole One is an oral capsule which contains the active ingredient fluconazole.

Chemists' Own Femazole Vaginal Cream contains the active ingredient clotrimazole, both ingredients belong to a group of medicines called azole antifungals.

Chemists' Own Femazole One capsule is taken by mouth and works from the inside to prevent the growth of the fungi causing your infection; Chemists' Own Femazole Vaginal Cream provides soothing relief from external itching and irritation.

Ask your doctor or pharmacist if you have any questions about why CHEMISTS' OWN FEMAZOLE DUO has been recommended for you. Your doctor or pharmacist may have recommended CHEMISTS' OWN FEMAZOLE DUO for another reason.

CHEMISTS' OWN FEMAZOLE DUO 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 DUO is addictive.

CHEMISTS' OWN FEMAZOLE DUO 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 thrush is a common name for vaginal candidiasis, an infection caused by a yeast-like fungus called *Candida albicans*.

Candida albicans is one of many organisms that live in the vagina. Your body's natural balance (immune system) normally keeps *Candida albicans* under control, but when this natural balance is upset, *Candida albicans* can multiply and can cause thrush symptoms.

Common symptoms of vaginal thrush include:

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

Things that may help you to 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.

Your doctor or pharmacist may have more information on things you can do to avoid thrush in the future.

2. What should I know before I use this medicine?

Warnings

Do not use this medicine if:

- you are allergic to fluconazole, clotrimazole, other azole antifungals such as miconazole, ketoconazole, itraconazole, econazole or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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;
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing;
- wheezing or shortness of breath.

Do not use CHEMISTS' OWN FEMAZOLE DUO if you are taking cisapride (Prepulsid), a medicine used to treat stomach problems. Combining CHEMISTS' OWN FEMAZOLE DUO with cisapride may cause serious side effects such as an abnormal heart rhythm.

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

FEMAZOLE DUO should not be used during pregnancy as it may affect your developing baby.

Do not use CHEMISTS' OWN FEMAZOLE DUO if you are breastfeeding. Fluconazole passes into breast milk and may affect your baby.

Do not use CHEMISTS' OWN FEMAZOLE DUO if the expiry date (EXP) printed on the pack has passed.

Do not use CHEMISTS' OWN FEMAZOLE DUO if the packaging shows signs of tampering; the capsule does not look quite right or the cream tube shows signs of tampering.

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

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives.
- take any medicines for any other condition

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

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

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 DUO if you are taking warfarin (e.g. Marevan, Coumadin), 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
- 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 or pharmacist about any of the above, tell them before you start using CHEMISTS' OWN FEMAZOLE DUO.

Using the Chemists' Own Femazole Vaginal Cream component of CHEMISTS' OWN FEMAZOLE DUO may reduce the effectiveness and safety of latex products, such as condoms and diaphragms. This effect is temporary and occurs only during treatment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

If you are taking cisapride (Prepulsid), a medicine used to treat stomach problems, do not use CHEMISTS' OWN FEMAZOLE DUO.

Some medicines may interfere with this medicine and affect how it works.

- warfarin (e.g. Marevan, Coumadin), a medicine used to prevent blood clots
- phenytoin (e.g. Dilantin), a medicine used to treat epilepsy
- cyclosporin (eg. Neoral) or tacrolimus (e.g. Prograf), medicines used to prevent organ transplant rejection or to treat certain problems with the immune system
- certain medicines used to treat diabetes such as: glibenclamide (e.g. Daonil, Glimel), glipizide (e.g. Minidiab, Melizide), glimepiride (e.g. Amaryl), gliclazide (e.g. Diamicon, Glyade)
- pioglitazone (e.g. Actos),
- rosiglitazone (e.g. Avandia)
- rifampicin (e.g. Rifadin, Rimycin) or rifabutin (e.g. Mycobutin),
- antibiotics used to treat infections
- theophylline (e.g. Nuelin), a medicine used to treat asthma
- midazolam (e.g. Hypnovel) and triazolam (e.g. Halcion), medicines used as sedatives or to treat anxiety
- zidovudine (e.g. Retrovir), a medicine used to treat AIDS
- hydrochlorothiazide (e.g. Dithiazide), a medicine 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 CHEMISTS' OWN FEMAZOLE DUO. CHEMISTS' OWN FEMAZOLE DUO 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.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist. Your doctor and pharmacist have more information on medicines to be careful with or avoid while using CHEMISTS' OWN FEMAZOLE DUO.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect this medicine.

4. How do I use this medicine?

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 pack, ask your doctor or pharmacist.

How to use

- For vaginal thrush in adults, only a single dose (1 capsule) is needed.
- Swallow the capsule whole with a glass of water. The capsule can be taken with or without food.
- Use the cream on the external irritated area 2-3 times a day to relieve the symptoms for as long as they last, usually not more than 3 days.
- Do not give CHEMISTS' OWN FEMAZOLE DUO to children under 18 years of age except under doctor supervision.
- Follow the instructions provided and use this medicine until your doctor tells you to stop. [for antibiotics, replace with 'Follow the instructions provided when this medicine was prescribed, including the number of days it should be taken.

If you forget to use this medicine

this medicine should be used regularly at the same time each day, week or month.

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 use too much this medicine

If you think that you have used too much this medicine, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26- Aust. or 0800 764 766 - N.Z.), or
- contact your doctor, or
- go to the Accident and Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using this medicine?

Things you should do

Call your doctor straight away if you:

- Before starting any new medicine, tell your doctor or pharmacist that you are using or have used CHEMISTS' OWN FEMAZOLE DUO.
- Tell all the doctors, dentists and pharmacists who are treating you that you are using or have used CHEMISTS' OWN FEMAZOLE DUO.
- Use effective contraception to prevent pregnancy while using CHEMISTS' OWN FEMAZOLE DUO.
- Immediately tell your doctor if you do become pregnant while using CHEMISTS' OWN FEMAZOLE DUO.
- If your symptoms do not improve after 3 days, tell your doctor or pharmacist.

Remind any doctor, dentist or pharmacist you visit that you are using this medicine.

Things you should not do

- Do not use CHEMISTS' OWN FEMAZOLE DUO to treat any other conditions unless your doctor or pharmacist tells you to.
- Do not give CHEMISTS' OWN FEMAZOLE DUO 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 using CHEMISTS' OWN FEMAZOLE DUO. People with AIDS or a weak immune system may be more prone to serious side effects of the skin..

Looking after your medicine

Keep CHEMISTS' OWN FEMAZOLE DUO 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.
- Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

If your doctor or pharmacist tells you to stop using

CHEMISTS' OWN FEMAZOLE DUO, or your medicine has passed its expiry date, ask your pharmacist what to do with it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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

CHEMISTS' OWN FEMAZOLE DUO helps most people and is generally well tolerated. However, it may have unwanted side effects in some people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">nausea (feeling sick), vomitingstomach pain, indigestiondiarrhoeaheadachemild burning, stinging or irritation immediately after applicationpruritis	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">unusual muscle stiffness causing poor control of movementfrequent infections such as fever, severe chills, sore throat or mouth ulcersbleeding or bruising more easily than normalpassing 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 tirednessan irregular heartbeat or palpitations.	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Very Serious side effects

Very Serious side effects	What to do
<ul style="list-style-type: none">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 breathsevere blisters and bleeding of the lips, eyes, mouth, nose and genitalsa severe rash with skin peeling, fever, chills and aching muscles.	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>These side effects are rare, but very serious and require urgent medical attention or hospitalization.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What this medicine contains

Chemists' Own Femazole One capsule	
Active ingredient (main ingredient)	One capsule is fluconazole 150 mg.
Each capsule also contains the following inactive ingredients:	<ul style="list-style-type: none">• gelatin• lactose monohydrate• maize starch• silica colloidal anhydrous• sodium lauryl sulfate• titanium dioxide• purified talc• patent blue V
Potential allergens	One capsule also contains sugars (as lactose) and sulfites (from gelatin).
Chemists' Own Femazole Vaginal Cream	
Active ingredient (main ingredient)	10 mg clotrimazole per gram of cream as the active ingredient.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Propylene glycol• Cetostearyl alcohol• Disodium edetate• Cetomacrogol 1000• Liquid paraffin• Dimethicone 100• White soft paraffin• Self-emulsifying glyceryl monostearate• Benzyl alcohol• Purified water
Potential allergens	This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What this medicine looks like

CHEMISTS' OWN FEMAZOLE DUO contains two components:

- Chemists' Own Femazole One capsule is a hard gelatin capsule with sky blue opaque body and cap. Each pack contains 1 capsule.
- Chemists' Own Femazole Vaginal Cream is a tube with a screwcap containing 10 g of a white cream.

CHEMISTS' OWN FEMAZOLE DUO - AUST R 302074

Who distributes this medicine

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
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