

FEMAZOLE DUO

Fluconazole 150 mg, one capsule
Clotrimazole 10mg/g, 10g tube cream

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using FEMAZOLE DUO.

This leaflet answers some common questions about FEMAZOLE DUO.

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 or pharmacist has weighed the expected benefits of you using this medicine 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.

What FEMAZOLE DUO is used for

FEMAZOLE DUO is used to treat a certain fungal infection called vaginal thrush.

FEMAZOLE DUO contains two components: FEMAZOLE ONE CAPSULE is an oral capsule which contains the active ingredient Fluconazole. FEMAZOLE DUO CREAM is a cream and contains the active ingredient clotrimazole. Both actives belong to a group of medicines calledazole antibiotics.

FEMAZOLE DUO CAPSULE is taken by the mouth and is used to treat vaginal thrush.

FEMAZOLE DUO CREAM is for external use and provides soothing relief from external itching and irritation.

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

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

Your doctor or pharmacist may have recommended FEMAZOLE DUO for another reason.

What is vaginal thrush

Vaginal thrush is a common infection caused by an overgrowth of yeast-like fungus called *Candida albicans*. This yeast lives naturally in the bowel and in small numbers in the vagina. It is mostly harmless, but thrush symptoms can develop if yeast numbers increase.

The following situations can influence the overgrowth of thrush:

- Diabetes
- Obesity
- Illness
- Fatigue
- Hormonal fluctuations (pregnancy, menstrual cycle, oral contraceptive pill, HRT)
- Prolonged use of antibiotics or steroids

Common symptoms of vaginal thrush include:

- itching, burning or soreness around the vagina
- vaginal discharge with a 'cottage cheese' appearance and yeasty smell
- swelling or irritation of the infected area

Things that may help you to avoid thrush in the future:

- wear clean cotton underwear and avoid wearing tight-fitting pants and synthetic underwear
- wash regularly, but do not wash and dry yourself harshly
- Wipe your bottom from front to back after going to the toilet. This will prevent the spread of *Candida albicans* from the anus to the vagina.
- Avoid using soap to wash the genital area. Soap substitutes can be used.
- Avoid using perfumed products, antiseptics, douches or perfumed sprays in the genital area.

Before you take FEMAZOLE DUO

When you must not take it

Do not use FEMAZOLE DUO if you have an allergy to:

- any medicine containing Fluconazole and clotrimazole
- medicines related to fluconazole such as miconazole, ketoconazole or itraconazole
- 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.

FEMAZOLE DUO should not be given 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 start taking this medicine, talk to your doctor.

Before you start to take it

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

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

- liver problems
- heart problems
- kidney problems.
- diabetes
- unexplained jaundice
- HIV or AIDS

If you are unsure about the cause of your symptoms, and if you have had thrush more than twice in the last six months.

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

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

- fever or chills
- abnormal or irregular vaginal bleeding or blood-stained discharge

- foul smelling and/or unusual coloured discharge
- vulval or vaginal sores, ulcer or blisters
- lower abdominal pain or burning when passing urine.

Using the clotrimazole cream component of 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.

Taking other medicines

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

Some medicines may be affected by FEMAZOLE DUO, or may affect how well it works. These include:

- some medicines for diabetes such as glipizide, tolbutamide or glibenclamide
- some antibiotics and antiviral drugs such as rifampicin, rifabutin or zidovudine
- some drugs used in problems with the immune system, such as cyclosporin or tacrolimus
- warfarin (used to stop blood clots)
- phenytoin (used to treat epilepsy)
- theophylline (used to treat asthma)
- some benzodiazepines such as midazolam
- hydrochlorothiazide (used for treating fluid problems).

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

How to use FEMAZOLE DUO

How to use it

Femazole Duo Capsule:

Adults

Swallow whole one capsule by mouth with a glass of water.

Only a single dose (1 capsule) is needed.

The capsule can be taken with or without food.

Femazole Duo Cream:

Wash your hands thoroughly before applying the cream. Apply gently to the irritated area of the skin outside the vagina, 2-3 times daily until symptoms are relieved, usually not more than 3 days. For external use only.

FEMAZOLE DUO is not recommended for use in children under 18 years of age.

If you use too much FEMAZOLE DUO (overdose)

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much FEMAZOLE DUO.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking FEMAZOLE DUO

Things you must do

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

If you become pregnant while using FEMAZOLE DUO, tell your doctor immediately.

Before starting any new medicine, tell your doctor or pharmacist that you are taking FEMAZOLE DUO.

Tell all the doctors, dentists and pharmacists who are treating you that you are using FEMAZOLE DUO.

Things you must not do

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

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

Things to be careful of

Tell your doctor immediately if you develop a rash while using FEMAZOLE DUO.

If you suffer from HIV or have a weakened immune system you may be more prone to serious side effects of the skin.

Side effects

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

FEMAZOLE DUO helps most people with vaginal thrush, 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 attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

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

- nausea or feeling sick, vomiting
- headache
- stomach pain, indigestion, diarrhoea

The clotrimazole cream component of Femazole Duo may cause mild burning, stinging or irritation immediately after applications. If you are concerned about any of these reactions, stop treatment and tell your doctor or pharmacist.

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 while taking FEMAZOLE DUO, 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 in swallowing or breathing (allergic reactions)
- shortness of breath, difficulty with breathing, wheezing, asthma (allergic reactions)
- sudden or severe itching, skin rash, hives (allergic reactions)
- flaking of the skin
- yellowing of the skin or eyes, also called jaundice

- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- fast or irregular heart beat
- severe abdominal cramps
- watery and severe diarrhoea,
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers.

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.

After using FEMAZOLE DUO

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 DUO in a cool, dry place where it stays below 25°C.

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

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

Heat and dampness can destroy some medicines.

Disposal

If your doctor 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

FEMAZOLE DUO contains two components:

- FEMAZOLE DUO CAPSULE contains a single hard blue gelatin capsule, filled with a white to off-white powder. .
- FEMAZOLE DUO CREAM contains a white opaque cream in a 10g tube.

Ingredients

The active ingredient in **FEMAZOLE DUO capsule** is Fluconazole 150 mg.

The capsules also contain:

- 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 capsule does not contain gluten, sucrose, tartrazine or any other azo dyes.

The ingredient in **FEMAZOLE DUO CREAM** is clotrimazole 10 mg/g

The cream also contains:

- Propylene glycol

- Cetomacrogol 1000
- Cetostearyl alcohol
- Paraffin - liquid and soft white
- Dimethicone 100
- Self-emulsifying Glyceryl monostearate
- Benzyl alcohol
- Disodium edetate
- Purified water

Sponsor

Sigma Pharmaceuticals (Australia) Pty Ltd
96 Merrindale Drive
Croydon Vic 3136
Tel: 03 - 9839 2800

The Australian Registration Numbers for FEMAZOLE DUO is AUST R 174773.

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