

AFEME DUO

contains the active ingredients Fluconazole 150 mg and Clotrimazole 10 mg/g

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AFEME DUO.

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 this medicine 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.

What AFEME DUO is used for

AFEME 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.

AFEME DUO contains two components: AFEME DUO Fluconazole is an oral capsule which contains the active ingredient fluconazole; AFEME DUO Clotrimazole Vaginal Cream contains the active ingredient clotrimazole, both of these ingredients belong to a group of medicines called azole antifungals.

AFEME DUO Fluconazole capsule is taken by mouth and works from the inside to prevent the growth of the fungi causing your infection;

AFEME DUO Clotrimazole Vaginal Cream provides soothing relief from external itching and irritation.

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

AFEME DUO is not recommended for children under 18 years of age.

There is no evidence that either component in AFEME DUO is addictive.

AFEME 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.

Before you use AFEME DUO

When you must not use it

Do not use AFEME DUO if you are allergic to medicines containing:

- fluconazole
- clotrimazole
- other azole antifungals such as miconazole, ketoconazole, itraconazole, econazole; or
- 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 AFEME DUO if you are taking:

- Cisapride (Prepulsid), a medicine used to treat stomach problems

- Astemizole, a type of antihistamine
- Pimozide, a medicine used to treat mental conditions
- Quinidine, a medicine used to treat abnormal heart rhythm.

Combining AFEME DUO with these medicines may cause serious side effects such as an abnormal heart rhythm.

Do not use AFEME DUO if you are pregnant, suspect you may be pregnant or if you may become pregnant during treatment. AFEME DUO should not be used during pregnancy as it may affect your developing baby.

Do not use AFEME DUO if you are breastfeeding. Fluconazole passes into breast milk and may affect your baby.

Do not use AFEME DUO if the expiry date (EXP) printed on the pack has passed.

Do not use AFEME 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.

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 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 AFEME DUO 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:

- 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 AFEME DUO.

Using the AFEME DUO Clotrimazole Vaginal Cream component of AFEME 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

If you are taking cisapride (Prepulsid), astemizole, pimozidine or quinidine, do not use AFEME DUO.

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

- warfarin (e.g. Marevan, Coumadin), a medicine used to prevent blood clots
- phenytoin (e.g. Dilantin), a medicine used to treat epilepsy
- ciclosporin (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 use 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)
- amphotericin B (amphotericin) (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
- terfenadine, an antihistamine.

Talk to your doctor about the need for an additional method of contraception while using AFEME DUO. AFEME 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 AFEME DUO.

How to use AFEME DUO

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 for help.

How to use it

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.

AFEME DUO is not recommended for children under 18 years of age.

If you use too much AFEME DUO (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have used too much AFEME DUO. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using AFEME DUO

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are using or have used AFEME DUO.

Tell all the doctors, dentists and pharmacists who are treating you that you are using or have used AFEME DUO.

Use effective contraception to prevent pregnancy while using AFEME DUO.

Immediately tell your doctor if you do become pregnant while using AFEME DUO.

If your symptoms do not improve after 3 days, tell your doctor or pharmacist.

Things you must not do

Do not use AFEME DUO to treat any other conditions unless your doctor or pharmacist tells you to.

Do not give AFEME 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 AFEME DUO. People with AIDS or a weak immune system 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 AFEME DUO.

AFEME 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. 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 this 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
- headache
- mild burning, stinging or irritation immediately after application
- pruritis

The side effects listed above are common and usually mild.

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; dark urine, pale stools; loss of appetite; unusual tiredness

- an irregular heartbeat 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. Other side effects not listed above may also occur in some people.

After using AFEME DUO

Storage

Keep AFEME 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.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store AFEME DUO or any other medicine in the bathroom or near a sink.

Do not leave your medicine in the car or on windowsills. Heat and dampness can destroy some medicines.

Disposal

If your doctor or pharmacist tells you to stop using AFEME DUO, or your medicine has passed its expiry date, ask your pharmacist what to do.

Product description

What AFEME DUO looks like

AFEME DUO contains two components:

AFEME DUO Fluconazole 1 capsule is a hard gelatin capsule with sky blue opaque body and cap. Each pack contains 1 capsule.

AFEME DUO Clotrimazole Vaginal Cream is a tube with a screw-cap containing 10 g of a white cream.

Ingredients

The active ingredient in the AFEME DUO Fluconazole capsule is fluconazole 150 mg.

Each capsule also contains the following inactive ingredients:

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

The capsule contains sugars (as lactose) and traces of sulfites.

The active ingredient in AFEME DUO Clotrimazole Vaginal Cream is 10 mg clotrimazole per gram of cream as the active ingredient.

The cream also contains:

- propylene glycol
- cetostearyl alcohol
- disodium edetate
- cetomacrogol 1000
- liquid paraffin
- dimeticone 100

- white soft paraffin
- self-emulsifying glyceryl monostearate
- benzyl alcohol
- purified water

The cream contains benzyl alcohol 1% w/w as preservative.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

AFEME DUO is supplied in Australia by:

Alphapharm Pty Limited
Level 1, 30 The Bond
30 - 34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian registration number:
AUST R 231084

This leaflet was prepared in January 2020.

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