

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Flufeme.

It does not contain all 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 risks of you taking this medicine against the benefits they expect it will 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 FLUFEME IS USED FOR

This medicine is used to treat vaginal thrush, a yeast infection of the vagina.

It contains the active ingredient fluconazole.

Fluconazole belongs to a group of medicines called azole antibiotics.

It works by preventing the growth of fungal organisms causing the infection in the vagina.

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

Your doctor or pharmacist may have recommended it for another reason.

This medicine is not addictive.

BEFORE YOU TAKE FLUFEME

When you must not take it

Do not take this medicine if you have an allergy to:

- fluconazole, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar antifungal medicines such as miconazole, ketoconazole or clotrimazole.

Some of the 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 this medicine if you are taking any of the following medicines:

- Cisapride, a medicine used to treat stomach problems
- Astemizole, a medicine used to control allergies
- Erythromycin, an antibiotic
- Amiodarone, a medicine used to treat irregular heartbeat
- Pimozide, an antipsychotic medicine used to treat mental illness
- Quinidine, a medicine used to treat abnormal or irregular heartbeat
- Terfenadine, a medicine used to control allergies

Do not take this medicine if you are pregnant or suspect you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not take this medicine if you are breastfeeding.

The active ingredient in Flufeme passes into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine after the expiry date printed on the pack 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.

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 or have had any of the following medical conditions:

- kidney problems
- liver problems
- heart problems
- diabetes
- thrush more than twice in the last 6 months.

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 him/her before you start taking Flufeme.

Taking other medicines

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

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

- terfenadine and astemizole, medicines used to control allergies
- cisapride, a medicine used to treat stomach problems
- warfarin and indanedione anticoagulants, a medicine used to stop blood clots, as bleeding or bruising may occur
- phenytoin or carbamazepine, medicines used to control epilepsy
- theophylline, a medicine used to treat asthma
- medicines used for sedation, such as midazolam
- hydrochlorothiazide, used as a fluid tablet or to treat high blood pressure
- birth control pills
- medicines used to control the immune system such as cyclosporin, tacrolimus, sirolimus, everolimus or prednisone
- some antiviral and antibiotic medicines including rifampicin, rifabutin, zidovudine, amphotericin B and erythromycin
- medicines used to treat diabetes such as glimepiride, gliclazide, glipizide,

tolbutamide and glibenclamide, pioglitazone or rosiglitazone

- cyclophosphamide, a medicine used to treat some cancers
- NSAIDs such as naproxen, diclofenac and celecoxib
- opioid pain killers such as alfentanil, fentanyl and methadone
- losartan, a medicine used to treat high blood pressure
- calcium channel blockers, medicines used to treat high blood pressure and angina
- cholesterol-lowering medicines, such as atorvastatin, fluvastatin or simvastatin
- quinidine, a medicine used to treat abnormal or irregular heart beat
- pimozide, an antipsychotic medicine, used to treat mental illness
- halofantrine, a medicine used to treat malaria
- antidepressants such as amitriptyline and nortriptyline.

These medicines may be affected by Flufeme, or may affect how well it works. 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 this medicine.

HOW TO TAKE FLUFEME

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

Flufeme is not recommended for children.

How much to take

The treatment for thrush is one Flufeme capsule.

How to take it

Swallow the capsule whole with a glass of water.

When to take Flufeme

This medicine can be taken before, with or after food and can be taken at any time of the day.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Flufeme. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING FLUFEME

Things you must do

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

Things that may help you avoid thrush in the future:

- after urinating, the toilet tissue should be used as a blotter, rather than used with a forward or backward motion. Similarly, to avoid the possibility of spreading organisms from the rectum to the vaginal tract after a bowel movement, a wiping motion away from the vagina should be used when applying toilet tissue.
- underwear, night attire, towels and linen should be changed daily
- 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.

Things you must not do

Do not take Flufeme to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give your medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful driving or operating machinery until you know how Flufeme affects you.

This medicine may cause dizziness or seizures occasionally in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well after you have taken Flufeme.

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 lists 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 or feeling sick
- stomach pain
- diarrhoea
- vomiting
- headache
- indigestion.

These are the more common side effects of the medicine. They are usually mild and short-lived.

If any of the following happen, 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
- asthma, wheezing, shortness of breath or difficulty breathing
- sudden or severe itching, skin rash, hives
- fits or seizures
- fast or irregular heartbeat

- yellowing of the skin or eyes, also called jaundice.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are usually rare.

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

Other side effects not listed above may also occur in some people.

AFTER TAKING FLUFEME

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Flufeme or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

Return any unused or out of date medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Flufeme comes in one type of capsule:

Flufeme 150 mg - capsules with a white cap and white body, printed with FC150.

Available in blisters of 1 capsule.

Ingredients

Active ingredient:

Flufeme 150 mg - 150 mg fluconazole

Inactive ingredients:

- lactose monohydrate
- maize starch
- magnesium stearate
- colloidal anhydrous silica
- sodium lauryl sulfate
- titanium dioxide
- gelatin
- black monogramming ink (107581 or 2328).

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

Novartis New Zealand Ltd
PO Box 99102
Newmarket
Auckland 1149
Tel: 0800 354 335

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Australian Register Number

150 mg capsule: AUST R 132827 (blisters)