

Thrush Femme 1% w/w Cream

Clotrimazole

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- You must talk to a doctor if you do not feel better or you feel worse after 7 days.

IN THIS LEAFLET

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1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR

This medicine contains Clotrimazole which belongs to a group of medicines called anti-fungals, which act to treat infections caused by fungi.

It can be used to treat the external symptoms of thrush (vulval candidiasis) and may also be used by the woman's sexual partner to treat associated penile thrush (candidial balanitis).

Thrush is a common infection caused by a yeast (or fungus), which may live harmlessly in the vagina without you even noticing it. However, in certain circumstances, it may develop into an infection in the vagina and symptoms may spread to the surrounding area. The symptoms may include one or more of the following.

- itching of the vagina and surrounding area (the vulva)
- redness and swelling of the tissues of the vagina and vulva
- soreness of the vagina and vulva
- a white non-smelling discharge from the vagina.

Thrush may be aggravated by sexual intercourse, but it is not a sexually transmitted disease. Sometimes, however, thrush can be passed to your partner through sexual intercourse.

If your partner has penile thrush he may have one or more of the following symptoms:

- soreness and redness of the penis
- tightness of the foreskin
- a white non-smelling penile discharge.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE THIS MEDICINE

This medicine can be used by adults between the ages of 16 and 60 years. However, some people should not use this medicine or should seek the advice of their pharmacist or doctor first.

Do NOT use:

- if you are allergic to any of the ingredients in this cream or any other anti-fungal medicine
- if you are pregnant or breastfeeding, unless your doctor tells you to.

Talk to your pharmacist or doctor:

- if this is the first time you have had these symptoms
- if you have had thrush more than twice in the last 6 months
- if you are under 16 years, or 61 years or older
- if you or your partner have ever been exposed to a sexually transmitted disease.
- if you have lower stomach pain, or pain or a burning sensation on passing urine.
- if you are a man and:
 - your sexual partner does not have thrush
 - you have an abnormal discharge or leakage from your penis
 - you have sores, ulcers or blisters on your penis
- if you are a woman and:
 - you have any abnormal or irregular vaginal bleeding, or a blood stained discharge
 - you have sores, ulcers or blisters on your vulva or vagina.

Other important information

Information about some of the ingredients in this medicine: Cetyl alcohol and stearyl alcohol in the cream may cause local skin reactions (e.g. contact dermatitis).

Thrush Femme Cream contains benzyl alcohol.

This medicine contains 1 mg benzyl alcohol in each 100 mg.

Benzyl alcohol may cause allergic reactions.

Benzyl alcohol may cause mild local irritation.

The ingredients in the cream may affect the latex used in contraceptives such as condoms and diaphragms. This may reduce the effectiveness of the contraceptives. You should therefore use other methods of contraception for at least 5 days after using the cream.

You can help the treatment to work if you follow these simple self-help tips:

- although the infected area will itch, do not scratch as this will damage the surface of the skin and cause the infection to spread further
- keep the affected areas of the skin clean
- pay particular attention to drying the skin but avoid excessive rubbing.

To help prevent thrush from coming back once you have treated it, follow these simple steps:

- wash daily
- wear cotton underwear and loose fitting clothing
- try to avoid wearing tights, nylon underwear and tight fitting clothing
- after going to the toilet, wipe yourself from the front to the back, as a thrush infection may be transferred from the bowel
- try to avoid washing with perfumed soaps or using vaginal deodorants
- do not rub hard with sponges or flannels and avoid hot baths with strong perfumed oils
- change your sanitary protection regularly.

Taking other medicines

Before you use this medicine, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time. If you are unsure about interactions with any medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

3. HOW TO USE THIS MEDICINE

Check that the tube seal is not broken before first use. If it is, don't use the cream.

Pierce tube seal with end of cap.

Age	How much to use	How often to use it
Adults aged 16 to 60 years	Apply a thin layer to the affected area	Two or three times a day for 2 weeks

For use on the skin only. For women, apply the cream to the vulva and surrounding area. For men, apply the cream to the penis.

Do not use on children under 16 years, or if you are an adult of 61 years or older, unless your doctor tells you to.

Do not use more than the amount recommended above.

If symptoms do not go away within 7 days talk to your doctor.

If you have thrush more than twice in six months you must see your doctor.

Accidental ingestion

If anyone accidentally swallows some of the cream talk to a doctor or go to your nearest hospital casualty department straight away. Take your medicine and this leaflet with you.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Thrush Femme Cream can cause side effects, although not everybody gets them.

If you get any of these serious side effects, stop using the cream. See a doctor at once:

- difficulty breathing, feeling dizzy, fainting, red raised itchy skin rash (severe allergic reactions).

These other effects are less serious. If they happen talk to your pharmacist:

- irritation, discomfort, pain or a burning or stinging sensation
- other allergic skin reactions such as itchy rash, swelling, peeling or flaking of the skin, blisters.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE THIS MEDICINE

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton. The date refers to the last day of that month.

If you have any cream left after that date return it to your nearest pharmacy for safe disposal.

6. FURTHER INFORMATION

What Thrush Femme Cream contains

This cream contains Clotrimazole 1 % w/w which is the active ingredient. As well as the active ingredient the cream also contains sorbitan stearate, polysorbate 60, cetyl palmitate, stearyl alcohol, cetyl alcohol, 2-octyldodecanol, benzyl alcohol and purified water.

What Thrush Femme Cream looks like and contents of the pack

The pack contains 20g of white cream.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:

TEVA UK Limited, Eastbourne, BN22 9AG.

Company responsible for manufacture:

Thornton & Ross Ltd., Linthwaite, Huddersfield, West

Yorkshire, HD7 5QH, UK.

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