

## CLOTRIMAZOLE 1 % w/w CREAM

### PACKAGE LEAFLET: INFORMATION FOR THE USER

The name of your medicine is Clotrimazole 1 % w/w cream, which will be referred to as 'Clotrimazole' or 'Clotrimazole cream' throughout this leaflet.

**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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better, or if you feel worse, after 7 days.

### IN THIS LEAFLET:

1. What Clotrimazole cream is and what it is used for
2. Before you use Clotrimazole cream
3. How to use Clotrimazole cream
4. Possible side effects
5. How to store Clotrimazole cream
6. Further information

## 1 WHAT CLOTRIMAZOLE CREAM IS AND WHAT IT IS USED FOR

Clotrimazole cream is a cream that is applied to the skin. It contains clotrimazole as the active ingredient, which is an antifungal. Clotrimazole cream is used for the treatment of skin infections caused by dermatophytes (a group of fungi that cause skin diseases).

Clotrimazole cream can be used to treat:

- ringworm infections
- paronychia (an infection of the fingernail or toenail)

- pityriasis versicolor (a rash caused by a yeast fungus)
- erythrasma (reddish brown scaly patches on the skin)
- intertrigo (a rash in body folds)
- fungal nappy rash
- candidal vulvitis (thrush of the vulva)
- candidal balanitis (thrush of the penis).

## 2 BEFORE YOU USE THIS MEDICINE

**Do NOT use Clotrimazole cream if:**

- You are allergic (hypersensitive) to clotrimazole or any of the other ingredients of Clotrimazole cream (see list of ingredients in Section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- Do not use this cream to treat scalp or nail infections without advice from a pharmacist or doctor.

**Take special care with Clotrimazole cream:**

- The cream contains cetyl alcohol and stearyl alcohol, which may cause a skin reaction (e.g. contact dermatitis)
- If you are using Clotrimazole cream for thrush of the vulva or penis, the cream may cause damage to condoms. You should take other precautions to prevent pregnancy for at least five days after using the cream.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding tell your doctor or midwife and they will decide if Clotrimazole cream is right for you. Follow their instructions carefully. Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Clotrimazole cream does not affect your ability to drive or use machines.

## 3 HOW YOU USE CLOTRIMAZOLE CREAM

### Dosage

Always use Clotrimazole cream exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

### • Adults, children and elderly:

The cream is applied to the affected area two or three times daily.

The duration of treatment depends on the infection being treated:

- Thrush infections need to be treated for at least two weeks
- Other infections need to be treated for at least one month.

### Accidental ingestion

If Clotrimazole cream is accidentally swallowed, you should consult a doctor immediately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4 POSSIBLE SIDE EFFECTS

Like all medicines, Clotrimazole cream can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body), or you feel dizzy or faint.

The following side effects have also been reported:

- blisters, itching, burning, stinging, discomfort, swelling, rash, irritation or peeling of skin.

### 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 at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

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

## 5 HOW TO STORE CLOTRIMAZOLE CREAM

**Clotrimazole cream should be kept out of the reach and sight of children.**

Do not use Clotrimazole after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer needed. These measures will help to protect the environment.

## 6 FURTHER INFORMATION

### What Clotrimazole cream contains:

The active substance is Clotrimazole 1 % w/w. The other ingredients are: Sorbitan Stearate, Polysorbate 60, Cetyl Palmitate, Stearyl Alcohol, Cetyl Alcohol, 2-Octyldodecanol, Benzyl Alcohol and Purified Water.

### What Clotrimazole cream looks like and contents of the pack

Clotrimazole cream comes in an aluminium tube with a plastic screw-on cap. It contains 20 g, 30 g, or 50 g of cream.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder

TEVA UK Limited, Eastbourne, BN22 9AG.

### Manufacturer

Pliva Hrvatska d.o.o (Pliva Croatia Ltd.)

Prilaz baruna Filipovića 25  
10 000 Zagreb  
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### APPROVALS

Signed by	Meaning of Signature	Server Date
Annette Huggett	Regulatory Affairs Approval	21-May-2015 03:30:59 PM