

## **PACKAGE LEAFLET: Information for the user**

### **CLODERM 1%**

Cream – 10 mg / 1 g

(Clotrimazole)

**Read the leaflet carefully before you start using this medicine because it contains important information.**

Always use this medicine exactly as described in this leaflet or as instructed by your doctor or pharmacist.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your pharmacist.
- If your symptoms get worse or if you have no improvement after 7 days, you should contact a doctor.
- 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. See section 4.

#### **In this leaflet:**

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

### **1. WHAT CLODERM 1% IS AND WHAT IT IS USED FOR**

Cloderm 1% cream contains the active substance clotrimazole which is a broad spectrum antimycotic.

Cloderm 1% is used in fungal infections of the skin caused by dermatophytes, yeasts (e.g. *Candida* species), molds and others, such as *Malassezia furfur* and in other infections caused by *Corynebacterium minutissimum*.

These can be expressed as fungal infections of the feet, fungal infections of the skin and skin folds, pityriasis versicolor, erythrasma, superficial candidiasis.

## **2. BEFORE YOU USE CLODERM 1%**

### **Do not use Cloderm 1% if:**

- you are hypersensitive to the active substance Clotrimazole or to any of the excipients of Cloderm 1% cream listed in section 6;
- you are hypersensitive to cetyl stearyl alcohol. It is recommended that instead of the cream, a cetyl stearyl alcohol free formulation may be used.

### **Take special care with Cloderm 1%**

Please talk to your doctor or pharmacist before using Cloderm 1%.

### **Taking other medicines**

Please contact your doctor or pharmacist if you are taking / using, have recently taken / used or intend to take / use other medicines, including those obtained without a prescription.

Clotrimazole reduces the efficacy of amphotericin and other polyene antibiotics (nystatin, natamycin).

### **Pregnancy and breastfeeding**

If you are pregnant or breast-feeding, if you think you are pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

As a precaution, clotrimazole should not be used in early pregnancy.

### **Driving and using machines**

There is no experience regarding the impairment of driving performance or the ability to operate machinery.

### **Important information about some of the excipients of Cloderm 1%**

Cloderm 1% cream contains cetyl stearyl alcohol and benzyl alcohol.

Cetyl stearyl alcohol may cause local skin irritation (e.g. contact dermatitis).

Benzyl alcohol may cause allergic reactions and mild local irritation.

### **3. HOW TO USE CLODERM 1%**

Always use Cloderm 1% according to the recommendation of your doctor or pharmacist and the instructions of this leaflet. Ask your doctor or pharmacist if you are not sure.

#### Posology

The cream should be applied thinly to the affected areas 2-3 times daily and rubbed in gently.

A strip of cream (½ cm long) is enough to treat an area of about the size of the hand.

#### **Duration of administration**

Regular and sufficiently long application of the cream is important for the success of the treatment.

The duration of treatment depends among other things on the extent and location of the disease.

To achieve a complete healing, the treatment should not be stopped right after the acute inflammatory symptoms, or subjective complaints disappear, but it should continue for a treatment duration of at least 4 weeks.

Pityriasis versicolor generally heals in 1 - 3 weeks and erythrasma in 2 – 4 weeks.

For athlete's foot, despite rapid subjective improvement, to prevent relapses, treatment should be continued about 2 weeks after the disappearance of symptoms. After each washing, the feet should be thoroughly dried (toe gaps).

#### **If you use more Cloderm 1% than you should**

You can continue treatment with the recommended doses. No side effects are expected from short-term overdose.

#### **If you forget to use Cloderm 1%**

Continue the treatment with the prescribed dosage (do not apply the cream more often or in larger quantities).

### **If you stop using Cloderm 1%**

Please note that it is important to have a sufficient duration of treatment with Cloderm 1% to ensure complete recovery and avoidance of recurrences.

Talk to your doctor or pharmacist before you stop treatment or finish it prematurely, for example: because of the side effects!

If you have any other questions about using this medicine, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Cloderm 1% can cause side effects, although not everybody gets them.

For the evaluation of side effects the following frequencies are used:

Very common	more than 1 user out of 10
Common	1 to 10 users out of 100
Uncommon	1 to 10 users out of 1.000
Rare	1 to 10 users out of 10.000
Very rare	Less than 1 user out of 10.000
Not known	Frequency cannot be estimated from the available data.

### **Possible side effects**

Often, skin reactions (e.g., burning, stinging) may occur.

In case of hypersensitivity to cetyl stearyl alcohol, skin allergic reactions may occur.

Benzyl alcohol may cause allergic reactions and mild local irritation.

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.

## **5. HOW TO STORE CLODERM 1%**

Keep out of the sight and reach of children!

Do not store above 25°C!

Do not use Cloderm 1% after the expiry date which is stated on the package and on the tube.

## **6. FURTHER INFORMATION**

### **What Cloderm 1% contains**

**The active substance** is clotrimazole.

1 g of cream contains 10 mg clotrimazole.

**The excipients** are: 2-octyl-1-dodecanol, cetyl stearyl alcohol, cetyl palmitate, polysorbate, sorbitan stearate, benzyl alcohol, PEG-stearate-glycol stearate, purified water.

### **Nature and content of container**

Box with a tube of 30 g.

### **Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

**This leaflet was last revised in November 2023.**