

## **Package leaflet: Information for the user**

### **Fungasil 10mg/g Cream**

#### **Terbinafine hydrochloride**

**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 or 14 days.

#### **What is in this leaflet**

1. What Fungasil 10 mg/g cream is and what it is used for
2. What you need to know before you use Fungasil 10 mg/g cream
3. How to use Fungasil 10 mg/g cream
4. Possible side effects
5. How to store Fungasil 10 mg/g cream
6. Contents of the pack and other information

#### **1. What Fungasil 10 mg/g cream is and what it is used for**

You must talk to a doctor if you do not feel better or if you feel worse after 7 or 14 days.

Fungasil 10 mg/g cream contains the active ingredient terbinafine hydrochloride and belongs to the group of antifungal preparations. Fungasil 10 mg/g cream is used to treat patients with fungal and yeast infections of the skin.

Fungasil 10 mg/g cream is active against certain yeasts and skin fungi, of which athlete's foot is the most well-known. See also section "3. How to use Fungasil 10 mg/g cream" for more information about the other fungal infections.

#### **2. What you need to know before you use Fungasil 10 mg/g cream**

##### **DO NOT use Fungasil 10 mg/g cream:**

- if you are allergic to terbinafine or any of the other ingredients of this medicine (listed in section 6). You can recognise hypersensitivity for example by red spots and lumps on the skin or itching.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before using Fungasil 10 mg/g cream.

Fungasil 10 mg/g cream is intended for external use only. It may be irritating to the eyes; therefore contact with the eyes should be avoided. In case of accidental contact with the eyes, rinse eyes thoroughly with running water.

#### **Children**

Fungasil 10 mg/g cream is not recommended for use in children below 12 years of age due to limited experience in this age group.

This medicine should be kept out of the sight and reach of children.

#### **Other medicines and Fungasil 10 mg/g cream**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

This medicine is not known to affect any other medicines when it is applied to the skin. However, as a precaution you should avoid applying other medicinal products to the area you are treating at the same time.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy

You should not use Fungasil 10 mg/g cream if you are pregnant or planning to get pregnant. If you get pregnant whilst using this medicine, tell your doctor.

#### Breast-feeding

Because terbinafine passes into the breast milk, you should not use Fungasil 10 mg/g cream if you are nursing a child. In addition, infants must not be allowed to come into contact with any treated skin, including the breast.

### **Driving and using machines**

Fungasil 10 mg/g cream has no influence on the ability to drive and use machines when used as directed and only externally.

### **Fungasil 10 mg/g cream contains cetyl alcohol and stearyl alcohol**

These may cause local skin reactions (e.g. contact dermatitis).

### **3. How to use Fungasil 10 mg/g cream**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This medicine is intended for external use only.

The opening of the tube is sealed with aluminium. You can break the seal with the inverted top of the tube, exerting slight pressure. Before applying the cream, the skin must be carefully washed and dried.

Apply just enough cream to form a thin layer on the affected skin and surrounding areas. Rub the cream in gently. If the treated area is in a skin fold (under the breasts, between the toes or fingers, in the groin or between the buttocks) the skin should be covered with sterile gauze, especially at night. Wash your hands afterwards, unless the treated area is on your hands.

#### Adults and adolescents (12 years and older)

Duration and frequency of treatment

- Athlete's foot (*Tinea pedis*): once a day for one week.  
The symptoms that can be associated with athlete's foot are itching, redness and scaling between the toes and on the soles of the feet. Cracks sometimes also appear (particularly between the toes) and oozing blisters can occur as well. Athlete's foot usually produces an unpleasant odour.
- Ringworm (*Tinea corporis*): once a day for one week.  
Ringworm consists of slowly growing, itchy, red and scaling ring-shaped patches that can be dispersed over the body.
- Skin fungus (*Cutaneous candidiasis*): once a day for 1 to 2 weeks.  
Candida is a species of yeast that can cause an infection of the skin in certain circumstances. Often the skin abnormalities are located in warm, damp areas such as the groin or under the breasts. The symptoms consist of itching, redness and scaling.
- Pityriasis versicolor: 1 to 2 times a day for 2 weeks.

The yeast that causes pityriasis versicolor is *Malassezia furfur*. An infection with this yeast mainly occurs on the shoulders and the upper part of the trunk and upper arms. The symptoms consist of slightly itchy and slightly scaling patches. In people who are fairly sun-tanned, the patches are usually lighter than the rest of the skin, and in people who have been exposed to little or no sun, the spots are usually light brown.

An improvement of the symptoms usually occurs after a few days. Irregular use or premature cessation of therapy increases the chance of the symptoms recurring. If no improvement has occurred after 1 to 2 weeks, contact your doctor or pharmacist.

#### Elderly

There is no evidence that elderly patients require a different dose or will suffer different side effects from younger patients.

#### Children

Fungasil 10 mg/g cream is not recommended for use in children below 12 years of age due to limited experience in this age group.

#### **If you use more Fungasil 10 mg/g cream than you should**

If you have used too much Fungasil 10 mg/g cream, this will not cause any harm, but contact your doctor or pharmacist if you are uncertain.

If someone, e.g. a child, swallows Fungasil 10 mg/g cream accidentally, adverse effects similar to those observed with an overdose of tablets containing terbinafine (e.g. headache, nausea, bellyache and dizziness) are to be expected. In this case, contact your doctor or poison information centre.

#### **If you forget to use Fungasil 10 mg/g cream**

Continue the treatment without applying Fungasil 10 mg/g cream an extra time or using it more than normal.

#### **If you stop using Fungasil 10 mg/g cream**

If you suddenly stop using Fungasil 10 mg/g cream, the old symptoms can recur.

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

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

##### **Common** (may affect up to 1 in 10 people)

- Skin exfoliation, itching (pruritus)

##### **Uncommon** (may affect up to 1 in 100 people)

- Skin lesion, scab, skin disorder, pigmentation disorder, redness (erythema), skin burning sensation
- Pain, application site pain, application site irritation

##### **Rare** (may affect up to 1 in 1,000 people)

- Condition aggravated
- Eye irritation
- Allergic reactions such as itching (pruritus), rash, dermatitis bullous and hives (urticaria).
- Dry skin, dermatitis contact, eczema

##### **Not known** (frequency cannot be estimated from the available data)

- Rash
- Hypersensitivity

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Fungasil 10 mg/g cream**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after: “Exp“. The expiry date refers to last day of the month.

Store in the original package in order to protect from light.

Do not freeze.

Keep the tube tightly closed.

You can use Fungasil 3 months after first opening of the tube.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Fungasil 10 mg/g cream contains**

- The active substance is terbinafine hydrochloride.  
Each gram of cream contains 10 mg of terbinafine hydrochloride.
- The other ingredients are sodium hydroxide (E524), benzyl alcohol, sorbitan stearate (E491), cetyl palmitate, cetyl alcohol, cetostearyl alcohol, polysorbate 60 (E435), isopropyl myristate, purified water.

#### **What Fungasil 10 mg/g cream looks like and contents of the pack**

Fungasil 10 mg/g cream is presented in the form of a cream. The contents of the aluminium tube with a polyethylene screw cap are 7.5 g, 15 g or 30 g.

The cream is white to almost white.

Not all pack sizes may be marketed.

#### **Marketing authorisation holder and manufacturer:**

Marketing authorisation holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Gedeon Richter Plc, Gyömrői út 19-21, H-1103 Budapest, Hungary

#### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Finland:	Terbistada 10 mg/g
Ireland:	Fungasil 10 mg/g cream
Italy:	Terbinafina EG 1% crema
The Netherlands:	Terbinafine HCl CF 10 mg/g crème, crème
Sweden:	Terbisil 10 mg/g kräm

**This leaflet was last revised in July 2015.**