



Patient Information Leaflet

FLUNAZOL 0.5% GEL

FLUCONAZOLE

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Flunazol Gel is and what it is used for
2. What you need to know before you use Flunazol Gel
3. How to use Flunazol Gel
4. Possible side effects
5. How to store Flunazol Gel
6. Contents of the pack and other information

1. What Flunazol Gel is and what it is used for

Flunazol Gel contains Fluconazole, which is an antifungal agent belonging to a class of agents called triazoles.

Flunazol Gel is indicated for the topical treatment of dermatomycosis (dermal fungal infection) caused by dermatophytes, yeasts and moulds, in particular Tinea pedis, Tinea corporis, Tinea cruris, Tinea versicolor and Candidiasis.

2. What you need to know before you use Flunazol Gel

Do not use Flunazol Gel

- If you are allergic to Fluconazole or related triazole compounds or to any other ingredient included in this medicine (see section 6).
If any of the above applies to you, do not use Flunazol Gel and talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine.

Use special care with Flunazol Gel:

- If you are pregnant or breast-feeding. If any of these apply to you, talk to your doctor.
- This medicine is not intended for ophthalmic use.
- This medicine is intended for external use only.

Other medicines and Flunazol Gel

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There is no clinical evidence of drug interactions with Flunazol Gel until date.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. This medicine is not recommended for pregnant woman and your doctor may choose another treatment for you.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. This medicine is not recommended for mothers who are breast-feeding and your doctor may choose another treatment for you if you wish to breast-feed.

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.

Driving and using machines

Flunazol Gel is unlikely to affect your ability to drive or use machines.

3. How to use Flunazol Gel

Always use this medicine exactly as your doctor has told you. You should check with your doctor if you are not sure.

Apply Flunazol Gel once daily. Massage gently the affected area of the skin. The duration of treatment varies according to the nature of the pathogen and the location of infection. For the majority of patients, the usual treatment duration is 1 to 3 weeks. Your doctor may extend this period to 6 weeks in the case of resistant infections.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them. Flunazol Gel is generally well tolerated. In rare cases it can cause skin irritations.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Flunazol Gel

- Keep this medicine out of the sight and reach of children.
 - Do not use Flunazol Gel after the expiry date. The expiry date refers to the last day of that month.
 - Do not store above 30°C.
 - Store in the original package.
 - Do not use any Flunazol Gel pack that is damaged.
 - Do not throw away any medicines via wastewater. 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 Flunazol Gel contains

The active substance in Flunazol Gel is Fluconazole. Each gram of Flunazol Gel contains 5 mg Fluconazole. Each tube contains 20 g of this gel.
The other ingredients are: Sodium hydroxide, carbomer, propylene glycol, polysorbate 80, methyl paraben, ethanol, purified water.

What Flunazol Gel looks like and contents of the pack

Flunazol Gel is a transparent gel. Flunazol Gel is available in tubes, each containing 20 g of 0.5% gel.

Marketing Authorisation Holder and Manufacturer

Pharmaline, sal – Lebanon
P.O. Box 90201 Jdeidet-El-Metn, Lebanon
Contact us: pharmaline@maliagroup.com

Registration No for Flunazol Gel in Lebanon: 24931/07

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Council of Arab Health Ministers
Union of Arab Pharmacists

The leaflet was last revised in February 2014

