

PACKAGE LEAFLET: INFORMATION FOR THE USER**Flenazole[®]**

Fluprednidene acetate + Miconazole nitrate (0,1% + 2%) w/w, cream

1. IDENTIFICATION OF THE MEDICINAL PRODUCT**1.1. Trade name****Flenazole[®]****1.2. Composition****Active substance(s):** Fluprednidene acetate and miconazole nitrate.**Excipients:** Dimethicone, Triglycerides medium chain, White soft paraffin, Glyceryl monostearate 40-50%, Stearyl alcohol, Glyceryl monostearate, Macrogol stearate 5000, Propylene glycol, Water purified.**1.3. Pharmaceutical form**

Cream for external use.

1.4. Quantitative compositionEach g of **Flenazole[®]** contains 1 mg fluprednidene acetate and 20 mg miconazole nitrate.**1.5. Nature and content of container**

- Each carton box contains tube of 20 g cream for external use and a leaflet
- Each carton box contains tube of 50 g cream for external use and a leaflet

1.6. Pharmacotherapeutic group

Topical anti-inflammatory and antifungal (ATC: D01AC20).

1.7. Marketing Authorization HolderTARGET PHARMA LTD, 54, Menandrou str., 104 31 Athens,
Tel.:30 210 5224830, Fax: 30 210 5224838,
e-mail: info@targetpharma.gr, <http://www.targetpharma.gr>**1.8. Manufacturer**

PROEL S.A. Greece

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE**2.1. General information****Flenazole[®]** contains two active substances: fluprednidene acetate and miconazole nitrate.

Fluprednidene acetate belongs to a class of potent glucocorticoids. ανήκει στην κατηγορία των ισχυρών γλυκοκορτικοστεροειδών. Several studies in animals and humans have proven the anti-allergic, anti-pruritic, anti-proliferative and anti-inflammatory properties of fluprednidene.

The second active substance of the medicine is miconazole nitrate, an anti-fungal agent, an imidazole.

Miconazole has been proven effective against dermatophytes *Candida* spp, *Pityrosporum* spp, *Torulopsis glabrata*, *Aspergillus* spp, Dimorphic fungi, *Cryptococcus neoformans*.

Miconazole nitrate has also antibacterial effect against some Gram positive bacilli and cocci.

2.2. Indication

Flenazole[®] cream is indicated for the treatment of superficial inflammatory dermatomycoses (caused by dermatophytes, blastomycins and/or yeasts). It is also indicated for the treatment of eczema superinfected by fungi.

Flenazole[®] is indicated for the initiation of treatment. As soon as inflammatory symptoms retreat treatment may continue with an anti-fungal cream (containing only miconazole nitrate as active), if this is needed.

2.3. Contraindications

Flenazole[®] cream should not be used in some skin conditions such as syphilis or tuberculosis, in infections caused by certain viruses (herpes simplex, herpes zoster, chickenpox), vaccination reactions, in perioral dermatitis, rosacea, acne and in primary suppurative skin infections.

Flenazole[®] cream should not be used in cases of hypersensitivity to the active substance or any of the excipients.

Flenazole[®] cream should not be applied around the eyes, eyelids, on thin skin, on wounds or ulcers. Application to mucous membranes should be avoided.

2.4. Special warnings and precautions for use

Flenazole[®] should not be used for long treatments, in extensive skin areas or under occlusive dressing.

2.4.1. Pregnancy and lactation

Flenazole[®] should be used with caution during pregnancy and lactation as well as in infants.

2.4.2. Effect on the ability to drive or use machines

There is no effect in the ability of driving or using machines.

2.4.3. Special warnings about the excipients

None.

2.5. Interactions with other medicines or substances

There are no known interactions when the product is applied topically.

2.6. Posology

Flenazole[®] cream is applied to the affected area once or twice a day, via gentle massage of the affected area.

Flenazole[®] cream should be used for one additional week after the retreat of the symptoms.

2.7. Overdose – Management

Prolonged and extensive use may lead to skin irritation and atrophy, as well as suppression of the adrenal cortex, due to increased absorption. Irritation and its action on the adrenal cortex, disappear upon discontinuation of treatment. Skin atrophy may persist.

If accidental ingestion of the product occurs, no special measures are needed, as the amount of the active ingredients is rather small and the activity of fluprednidene is rapidly reduced.

2.8. Possible side effects

Long term treatment with **Flenazole**[®] cream is generally well tolerated. Prolonged therapy and/or application in large skin areas especially with occlusive dressing can cause skin lesions such as atrophy, telangiectasia, extensive striae, steroid acne, perioral dermatitis, hypertrichosis, depigmentation and hormonal disorders.

In rare isolated cases allergic or irritant skin reactions may be caused, that can lead to skin rashes

Poison Center Athens, Tel.: +30 210 77 93 777

In case you experience a side effect caused by this medicine, you should report it to your doctor or pharmacist or any other health care professional or directly to the National Drug Organization (284 Mesogeion Av. 15562, Cholargos, Athens Greece, www.eof.gr).

2.9. What should you know if you miss a dose

Take the dose as quickly as possible. However, if it is almost time for the next dose, skip the missed dose and continue your regular schedule.

Do not double doses.

2.10. What should you know about the expiration date

The expiration date is mentioned in the container and the tube.

Do not take this medicine after this date.

2.11. Special precaution for storage

Store it below 25°C and keep away from children.

2.12. Date of last revision of the text

14/12/2012.

3. INFORMATION FOR THE RATIONAL USE OF MEDICINES

- This medicine has been prescribed for you by your doctor only for your particular medical problem. Do not pass it on to others or use it in other medical problems without taking previously advice by your doctor.
- If any problem with the medicine occurs during the treatment contact immediately your doctor or your pharmacist.
- If you have any questions about the information concerning the medicine that you use or you need better advising for your medical problem do not you hesitate to ask this information from your doctor or your pharmacist.
- To be effective and safe the medicine, which is prescribed for you, it must be used according to the given information.
- For your safety and health it is necessary to read carefully any information concerning your prescribed medicine.
- Do not store the medicines in bath lockers, because the heat and moisture can degrade the medicine and make it harmful for your health
- Do not keep the medicine, which you do not need any more or those that have expired.
- Keep all medicines in safe place out of the reach and sight of children.

4. PRESCRIBING INFORMATION

This product is subjected to medicinal prescription.