

PACKAGE LEAFLET: INFORMATION FOR THE USER

Neo-Egmol[®]
2% w/w shampoo,
Ketoconazole

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

1.1. Trade name

Neo-Egmol[®]

1.2. Composition

Active substance: Ketoconazole.

Excipients: Sodium laureth sulfate, Disodium laureth sulfosuccinate, Coconut fatty acid diethanolamide, Lauryldimonium hydroxypropyl hydrolyzed collagen, PEG-120 Methyl glucose diolate, Parfum, Imidurea, Hydrochloric acid concentrated, Sodium hydroxide, Erythrosine sodium E127 CI 45430, Sodium chloride, Water purified.

1.3. Pharmaceutical form

Shampoo.

1.4. Quantitative composition

Each g of the shampoo contains 20 mg ketoconazole (2%).

1.5. Nature and content of the container

Each carton contains a bottle of 60 ml or 120 ml or 180 ml of shampoo colored red and a leaflet.

1.6. Pharmacotherapeutic category

Antifungal for local external use.

1.7. Marketing Authorization Holder

TARGET PHARMA LTD., 54 Menandrou st., 104 31 Athens Greece,
Tel.: +30 210 5224830, Fax: +30 210 5224838, E-mail: info@targetpharma.gr, www.targetpharma.gr

1.8. Manufacturer

MEDICHROM S.A.

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

2.1. General information

Neo-Egmol[®] is a medicine that is used for the treatment of scrub and itching associated with dandruff and skin infections of the scalp (e.g. Pityriasis Versicolor) caused by fungi and yeasts.

2.2. Indications

Treatment and prophylaxis of severe dandruff of the scalp (dandruff).

2.3. Contraindications

Do not use ketoconazole shampoo, if you are sensitive to it.
Sensitivity symptoms include itching and redness of the skin that occur after applying the shampoo.

2.4. Special warnings and precautions for use

2.4.1. General

- As with other shampoos, avoid contact with the eyes. If this happens rinse the eyes with water.
- Dandruff for which **Neo-Egmol**[®] is used is usually accompanied by hair loss. This may also occur with the use of **Neo-Egmol**[®] when used in such cases.
- Do not use this shampoo for a long time without the advice of your doctor.
- Irritation may occur when the shampoo is used at the same time or immediately after long term treatment with topical corticosteroids (see section 2.5).

2.4.2. Elderly

As with adults.

2.4.3. Pregnancy

Do not use ketoconazole shampoo during pregnancy.

2.4.4. Lactation

Do not use ketoconazole shampoo if you are breast-feeding.

2.4.5. Children

Do not use this shampoo in children under 15 years of age without the advice of a doctor.

2.4.6. Effect on the ability to drive

Not applicable.

2.4.7. Special warnings about the excipients

Not applicable.

2.5. Interactions with other medicines or substances

Corticosteroids (medicines like cortisone) in cream, lotion form:

If you are using such medicines, you may start treatment with **Neo-Egmol**[®], but do not discontinue the use of the topical corticosteroid abruptly but gradually. Otherwise your skin may react presenting redness and itching.

Continue your corticosteroid treatment as follows:

- Apply the usual amount for 1 week, several hours prior shampoo application.
- Gradually reduce the frequency in a 2-3 weeks interval.
- After that you may discontinue the topical corticosteroid application.

If you have any doubts ask your doctor or pharmacist.

2.6. Posology – instructions of use

Therapeutic treatment

- Twice per week for 2-4 weeks.

Prophylaxis

- Once every 1 or 2 weeks.

Instructions of use

1. Wet the hair.
2. Use adequate quantity of the shampoo until you have rich foam.
3. Gently massage the whole scalp and let the shampoo act for 3-5 minutes.
4. Rinse thoroughly the hair.

2.7. Overdose - Management

Although accidental ingestion of ketoconazole shampoo is not expected to consist of a serious event, you should inform the soonest possible your doctor or pharmacist or you may call in the **Poison Center of Athens, Tel: +30 210 7793777**.

Information for the doctor in case of overdose:

- In case of accidental overdose, the management may only be supportive according to signs.
- If ingested, no vomiting should be induced or perform gastric wash to avoid absorption.

2.8. Possible side effects

Local burning sensation, itching and greasy or dry hair may occur. Contact dermatitis may also be induced, so in such case the application of the shampoo should stop immediately. Usually grey-haired patients, especially those that use chemical treatment techniques (e.g. in a hair salon, hair-bleaching, perm etc.) they may show hair discoloration.

If you get any side effects, please talk to your doctor or pharmacist or any other health care provider or directly to the National Medicines Agency (284 Mesogion Av., 15562, Cholargos, Athens, Greece www.eof.gr).

2.9. What you should know in case you forget to take one dose

Not applicable.

2.10. What should the patient know about the expiration date

It is written in outer and inner packaging.
Do not use this medicine if this date has expired.

2.11. Special warnings about the storage of the product

Store at temperature below 25°C.

2.12. Date of last revision of this leaflet

14-12-2012.

3. INFORMATION FOR THE RATIONAL USE OF MEDICINES

- This pharmaceutical product was prescribed by your doctor to you, according to your medical history and condition. Do not pass the product to others or use it in any other condition even if the symptoms may appear the same and without receiving your doctor's or pharmacist's advice.
- If during treatment with this medicine you experience any problem or issue, contact immediately your doctor or pharmacist.
- If you have any questions regarding the information for this product, its use or about the medical condition that you suffer, you should ask your doctor or pharmacist.
- This product will be safe and effective if it is used exactly according to instructions provided.
- For your own safety it is highly recommended that you read carefully all information provided for the prescribed medicine.
- Do not store medicines in bathroom lockers, as the high temperature and the humidity may degrade the product which may be harmful to your health.
- Store the product in the original packaging.
- If your doctor instructed you to stop the use of this product, dispose the remaining product and do not use it.
- Do not keep the medicine you do not need any more or those that are expired.
- Keep all medicines in safe place out of reach and sight of children.

4. PRESCRIBING INFORMATION

This product is not subjected to a medicinal prescription.