

Noreskin®

Azelaic acid, 20% cream

PACKAGE LEAFLET: INFORMATION FOR THE USER

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

1.1. Name: Noreskin® 20%

1.2. Composition: Active substance: Azelaic acid.

Excipients: Crodet S40 (Polyoxyl-40-Stearate), Crodet GTCC, PEG-8 Caprylic-Capric Glycerides (Labrasol), Benzoic Acid, Glycerine 85%, Propylene Glycol, Sepigel 305, Water purified.

1.3. Pharmaceutical form: Cream

1.4. Strength of active substance: 1 g of cream contains 0.20 g of azelaic acid.

1.5. Description - Packaging: Noreskin® 20% cream is a white, oily cream available in tubes containing 30 g or 60 g.

1.6. Pharmacotherapeutic group: Preparation against acne for topical use.

1.7. Marketing Authorisation Holder: TARGET PHARMA, 54 Menandrou Street, 10431 Athens, Greece. Tel.: +30 210 5224830 Fax: +30 210 5224838, Email: info@targetpharma.gr, www.targetpharma.gr

1.8. Manufacturer: STASINOS C. SIKALIAS – LABORATORIES

2. WHAT YOU NEED TO KNOW ABOUT THE MEDICINAL PRODUCT PRESCRIBED BY YOUR DOCTOR

2.1. General information: Noreskin® 20% cream acts against the bacteria called *Propionibacterium acnes*, which play an essential part in causing acne. It also reduces growth of the keratin layer cells, which block the pores of the skin, causing blackheads and whiteheads.

2.2. Indications: For the relief of mildly to moderately severe common acne.

2.3. Contraindications: Hypersensitivity to azelaic acid or to any of the excipients, in particular propylene glycol.

2.4. Special warnings and precautions for use.

2.4.1. General: For external use only. Noreskin® 20% cream contains benzoic acid and propylene glycol, which may cause mild irritation of the skin and the mucous membranes. Caution should be exercised to avoid contact with the eyes, mouth and other mucous membranes, and relevant instructions must be given to patients. In the event of accidental contact, the eyes, mouth and/or affected mucous membranes must be rinsed with plenty of water. If the eye irritation persists, patients must seek medical advice. The hands should be washed after applying the cream.

2.4.2. Elderly: There are no special warnings.

2.4.3. Pregnancy: There are no data on the safety of azelaic acid during pregnancy. For this reason, its use during pregnancy should be avoided, unless deemed essential and there is no other suitable alternative treatment. Animal studies do not indicate harmful effects on the embryo after the use of azelaic acid during pregnancy.

2.4.4. Breastfeeding: There are no data on the safety of azelaic acid during breastfeeding. For this reason, its use when breastfeeding should be avoided, unless deemed essential and there is no other suitable alternative treatment. Infants should not come into contact with skin / breasts where azelaic acid has been applied.

2.4.5. Children: The safety and efficacy of Noreskin cream in children below the age of 12 years have not been established.

2.4.6. Effect on ability to drive and use machines: There are no known effects.

2.4.7. Special warnings for the excipients contained: Noreskin® 20% cream contains benzoic acid and propylene glycol, which may cause mild irritation of the skin and the mucous membranes. Do not use Noreskin cream if you are hypersensitive to the excipients of the products, in particular propylene glycol.

2.5. Interaction with other medicinal products and other forms of interaction: Interaction with other medicinal products has not been reported yet.

2.6. Dosage: Noreskin® 20% cream is indicated for use on the skin only. Before application, the skin should be washed thoroughly with water and dried. A mild skin cleanser may be used. Noreskin® 20% cream should be applied sparingly on the affected areas of the skin twice a day (morning and night) and rubbed on gently. Around 1 g = 4 cm of cream is adequate quantity for the whole area of the face. Closed or gauze covering should not be used and the hands should be washed after applying the cream. It is important to use the cream without interruption throughout the treatment period. During the first week of treatment, patients with sensitive skin should use Noreskin® 20% cream once a day (at night) and then continue treatment twice a day (morning and night). In the event of skin irritation (see section 2.8. "Side effects"), the quantity of the cream per application should be reduced or the frequency of use should be reduced to once a day until the irritation subsides. If necessary, treatment should be interrupted for a few days. The duration of use of Noreskin cream varies from person to person and also depends on the severity of the skin disorder. In general, a distinct improvement is visible within 4 weeks. To get the best possible results, Noreskin cream should be used regularly for several months depending on the clinical result, but no longer than 6 months. If there is no improvement within 1 month or if the acne worsens, the use of Noreskin cream should be interrupted and other treatment methods should be considered.

2.7. Overdose: Acute toxicity studies on lab animals do not indicate that any risk of acute intoxication is to be expected following a single skin application of an overdose (application over a large area under conditions favourable to absorption) or oral ingestion.

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2.8. Side effects: Local skin irritation (e.g. redness or peeling, itching or burn) may occur occasionally. In most cases, the irritation is mild and subsides as treatment continues. If the irritation of the skin is severe and persistent, the quantity of the cream per application should be reduced or the frequency of use of Noreskin cream should be reduced to once a day until the irritation subsides.

If necessary, treatment should be interrupted for a few days. Photosensitivity reactions have been very rarely reported. Furthermore, allergic skin reactions (e.g. rash) have been very rarely reported.

2.9. What you need to know if you miss a dose: If you forget to apply a dose, apply it as soon as you remember it. However, if it is close to the time of the next dose, then wait and apply directly the next Noreskin cream dose.

2.10. Expiry date of the product: The expiry date is stated on the packaging. Do not use the medicinal product after that date.

2.11. Special precautions for storage: Store below 25°C.

2.12. Date of revision of leaflet: 31/03/2021 (EOF circular texts 48640/9-8-2005)

3. INFORMATION ON THE PROPER USE OF MEDICINAL PRODUCTS

- Your doctor prescribed this medicine for your specific medical condition. Do not pass it on to others or use it for any other condition without first having consulted your doctor.
- If during treatment a problem with the medication occurs, immediately inform your doctor or pharmacist.
- If you have any questions regarding the information about the medicinal product you are taking or if you need to be better informed about your medical problem, do not hesitate to request this information from your doctor or pharmacist.
- For your medicinal product to be safe and effective, you must take it according to the instructions given to you.
- For your health and safety, it is necessary to carefully read all the information about the medicinal product given to you.
- Do not keep in bathroom cabinets, as the heat and humidity may alter the medicinal product and render it harmful for your health.
- Keep the medicinal products in their original container.
- Do not keep medicinal products you no longer need or which have expired.
- For increased safety, keep medicinal products in a safe place, away from children.

4. DISTRIBUTION METHOD: Medical prescription not required.

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