Target Pharma Ltd PIL_2616101_v. 01

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fusidic/Target®

2% w/w cream, fusidic acid

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

1.1. Trade name

Fusidic/Target®

1.2. Composition

Active substance: Fusidic acid.

Excipients: Butylated hydroxyanisole, Cetyl alcohol, Glycerol, Potassium sorbate, Paraffin liquid,

Polysorbate 60, White soft paraffin, Water purified.

1.3. Pharmaceutical form

Cream

1.4. Quantitative composition

1 g of cream contains 20 mg fusidic acid.

1.5. Nature and contents of container

Each carton contains a tube of 15 g cream for external use and a leaflet.

1.6. Pharmacotherapeutic category

Antibiotic.

1.7. Marketing Authorization Holder

ΤΑΡΓΚΕΤ ΦΑΡΜΑ, 54 Μενάνδρου st., 104 31 Athens Greece,

Tel.: +30 210 5224830, Fax: +30 210 5224838,

E-mail: info@targetpharma.gr, http://www.targetpharma.gr

1.8. Manufacturer

Pharmaceutical Industry PROEL Epam. G. Koronis S.A.

2. WHAT THE PATIENT SHOULD KNOW ABOUT THIS MEDICINE

2.1. General

Fusidic/Target[®] is an antibiotic active against Gram positive bacteria. *Stapphylococci sp.* resistant to penicillin are susceptible to **Fusidic/Target**[®].

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The effectiveness of topically applied **Fusidic/Target**® is based mainly on the strong antimicrobial action against microorganisms that cause skin infections, but also to the unique ability of Fusidic acid to permeate intact skin.

2.2. Indications

Treatment of skin infections caused by Staphylococci sp. and skin abscesses.

2.3. Contraindications

You should not take this medicine if you are allergic to fusidic acid and the derivative salts or if you are infected by resistant microorganisms such as *Pseudomonas aeruginosa*.

2.4 Special warnings and precautions for use

2.4.1. General

Long-term use should be avoided as there is a risk to develop resistant strains of bactria. Caution is needed as you should avoid contact with the eyes.

2.4.2. Elderly

Same as for adults.

2.4.3. Pregnancy

Safety of use during pregnancy has not been established. Consult your doctor before you use this medicine.

2.4.4. Lactation

Safety of use during lactation has not been established. Consult your doctor before you use this medicine.

2.4.5. Children

Consult your doctor.

2.4.6. Effects on the ability to drive and use machines

None.

2.4.7. Special warnings about the excipients

None.

2.5. Interactions with other medicines and substances

None.

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2.6. Posology

Fusidic/Target® cream is applied on the infected skin area 2-3 times daily, for a period not longer than 7 days.

2.7. Overdose - Management

Due to the external use of the product it is unlike to overdose. In case of accidental ingestion talk to your doctor.

Poison Center Athens, Tel.: +30 210 7793777

2.8. Possible side effects

Rare hypersensitivity cases have been reported presenting skin irritation and rash at the site of application.

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

If you forget to use your medicine, apply the next dose as soon as you remember. If it is about the time for your next dosage, do not use the forgotten dosage, continue your treatment as planned. Do not double dosages.

2.10 What should the patient know about the expiration date

Expiration date is mentioned in outer and immediate container. Do not use after the expiration date.

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.

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• 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 medicine is subjected to medicinal prescription.

