PACKAGE LEAFLET: INFORMATION FOR THE USER

Mupirocin/Target®
2% w/w ointmen
Mupirocin

1. IDENTIFICATIONOF MEDICINAL PRODUCT

1.1. Trade name

Mupirocin/Target® ointment 2% w/w.

1.2. Composition:

Active substance: Mupirocin.
Excipients: Polyethylene glycol 3350, Polyethylene glycol 400.

1.3. Pharmaceutical form

Ointment.

1.4. Quantitative composition

Each g of ointment **Mupirocin/Target®** contains 20 mg Mupirocin.

1.5. Nature and contents of the container

Carton containing tube of 15 g ointment for external use and a leaflet.
Carton containing tube of 30 g ointment for external use and a leaflet.

1.6. Pharmacotherapeutic group

Topical antibiotic (ATC: D06AX09).

1.7. Marketing Authorization Holder

TARGET PHARM, 54 Menandrou 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 SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

2.1. General Information

Mupirocin/Target® is an antibiotic that can be naturally found, and owns a chemical structure that differs from other antibiotics, a wide range of action and is administered topically.

Mupirocin/Target® is effective against microorganisms responsible for the majority of skin infections. It is mainly active against aerobes, gram positive bacteria such as:

- *Staphylococcus aureous* (including β-lactamace producing strains that are methicillin resistant)

- *Staphylococcus epidermis*
- other *Staphylococcus sp.* that are coagulase negative and including methicillin resistant strains
- *Streptococcus sp.*

2.2. Indications

Mupirocin/Target® is indicated for topical use in primary and secondary microbial skin infections caused by susceptible to mupirocin bacteria.

2.3. Contraindications

Hypersensitivity to mupirocin or to other ointments that contain polyethylene glycols.
Ointment is not intended for ocular or intranasal use or in conjunction with cannula.

2.4. Special warnings and precautions of use

When **Mupirocin/Target®** is used on the face, contact with the eyes should be avoided.
Polyethylene glycol can be absorbed through open wounds and skin lesions and is excreted through kidneys.
Like with other ointment containing polyethylene glycol, **Mupirocin/Target®** should not be used when the local conditions allows absorption of high quantities of polyethylene glycol, especially if the patient has moderate to severe renal impairment.
In the rare case of a reaction suggesting hypersensitivity or serious topical irritation caused by **Mupirocin/Target®** ointment, treatment should be discontinued and appropriate alternative treatment for the infections should be used.

2.4.1. Pregnancy

Fertility and toxicity studies in test animals showed that Mupirocin has no effect on the fetus or reproduction. However, there are no adequate data for the safety during pregnancy.

2.4.2. Lactation

It is not known if Mupirocin is excreted in breast milk. Lactation should be discontinued during **Mupirocin/Target®** administration.

2.4.3. Elderly

There are no restrictions other than renal impairment (see section Special warnings and precautions).

2.4.4. Special warnings about the excipients

See section 2.4.

2.4.5. Effects on the ability to drive and use machines

None known.

2.5. Interactions with other medicines or substances

Mupirocin/Target® should not be mixed with other formulations, as the anti-microbial effect is significantly decreased due to lower concentration to the new preparation.

2.6. Posology

Adults - Children - Elderly – Patient with liver disease:

A small amount of **Mupirocin/Target®** should be used in the infected area, up to 3 times a day for 10 days, depending on the response. Treated area may be covered with a gauze dressing if needed. Patients that don't show a clinical response within 3-5 days, should be re-evaluated. Duration of the treatment should not exceed 10 days.

Route and method of administration
Topical use (see section "Posology").

2.7. Overdose – Management

Cases of overdose have not been reported. In case of accidental ingestion of **Mupirocin/Target®** talk to your doctor.

2.8. Possible side effects

Mupirocin/Target® is generally well tolerated.
The following side effects have been rarely reported: itching, burning sensation, redness, stinging and dryness locally at the site of administration.
Skin sensitization to **Mupirocin/Target®** or ointment base has been rarely reported.

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

If you get any side effects, please talk to your doctor, or pharmacist or other healthcare professional or directly to the National Medicines Agency (Mesogion 284, 15562, Cholargos, www.eof.gr)

2.9. What should the patient know if a dose is missed

If you need to use this medicine regularly and you forget a dose, take it as soon as you remember. However if it is near the time for your next dose, continue to your next dose, skipping the missed.

Do not double the doses.

2.10. What should the patient know about the expiry date

Expiry date is written on the outer package and on the tube.
Do not use this medicine after the expiry date.

2.11. Special warnings about the storage of this product

Store at temperature below 25º C.

2.12. Date of last revision of the text

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 medicine is subjected to medicinal prescription.