PACKAGE LEAFLET: INFORMATION FOR THE USER

Salicylic/Target®
10% cutaneous solution
Salicylic acid

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

1.1. Trade name

Salicylic/Target® 10% cutaneous solution.

1.2. Composition

Active substance: 100 g cutaneous solution contain 10 g salicylic acid.
Excipients: Propylene glycol octanoate/decanoate, Propylene glycol.

1.3. Pharmaceutical form

Cutaneous solution.

1.4. Quantitative composition

1 g of cutaneous solution contains 100 mg salicylic acid.

1.5. Nature and content of the container

Carton box containing 100 ml bottle of solution, cap (nozzle) and leaflet.

1.6. Pharmacotherapeutic category

Antipsoriatic.

1.7. Marketing Authorization Holder

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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

2.2. Indications

Initial treatment of mild to moderate scalp psoriasis.

2.3. Contraindications

- Sensitivity to salicylic acid, salicylic derivatives or any of the excipients of **Salicylic/Target®**.
- Pregnancy.

- Newborns, infants and children under 12 years of age.
- Patients with kidney impairment or liver failure. Patients with kidney impairment may use a product containing lower strength of active substance.
- **Salicylic/Target®** should not be used in non-stabilized inflammatory psoriasis where the skin is inflammated, itching and sun-sensitive.

2.4. Special warnings and precautions for use

2.4.1. General

Maximum adult daily dose of salicylic acid of 2g, should not be used for periods longer than a week. Avoid contact with the eyes, nose, mucus membranes and healthy skin. Caution is needed during treatment to elderly patients, to avoid systemic effect of salicylic acid.

2.4.2. Pregnancy and lactation

Pregnancy:
<u>During the first and second trimester:</u>
Safety of **Salicylic/Target®** during pregnancy has not been established. Administration of **Salicylic/Target®** should be avoided during the first and second trimester of pregnancy.
<u>During the third trimester:</u>
During the third trimester of pregnancy, all inhibitors of prostaglandin synthesis, including salicylic acid, may cause cardiopulmonary and renal toxicity to fetuses. At the end of pregnancy, prolonged bleeding may occur to both mother and child.
Therefore, **Salicylic/Target®** is contraindicated during the last trimester of pregnancy.

Lactation:
Following oral administration, salicylic acid can be traced in low concentration in breast milk. However, **Salicylic/Target®** may be used during lactation as topical treatment but should not be used on the breast.

2.4.3. Children

Salicylic/Target® should not be used in newborns, infants and children younger than 12 years.

2.4.4. Effects on the ability to drive and use machines

Not applicable

2.4.5. Special warnings about the excipients

Not applicable

2.5. Interaction with other medicines or substances

Salicylic acid may increase permeability (absorption) of other topically applied medicines and should not be used in combination with other medicines when applied on the scalp. Systemically absorbed salicylic acid may induce toxicity of methotrexate and enhance sulfonylureas hypoglycemic effect. Salicylic acid is incompatible with several active and inactive excipients that affect release of active substances. These include the following: acriflavine salts, lead salts, camphor, chloral hydrate, iron salts, ethacridine salts, gelatin, iodine, iodide, iodoform, beta-naphthol, polyethylene glycol, resorcinol, zinc oxide.

2.6. Posology and method of administration

A thin layer of 8-10 ml **Salicylic/Target®** is applied on dry skin of the scalp using the applicator (nozzle).

The applied product should remain for 10 to 30 minutes and then should be rinsed with excess hot water.

Salicylic/Target® is applied 2 to 3 times per week, but not on consecutive days. Treatment usually lasts 3 to 4 weeks. The doctor will decide the duration of the treatment needed.

Maximum dosage of 2g salicylic acid should not be used for intervals longer than one week.

The solution is applied with the aid of the applicator (nozzle).

Caution is needed so that **Salicylic/Target®** will not get in contact with the eyes and nasal cavity.

Additionally, caution is needed to prevent the solution to exceed the scalp.

After treatment, the cutaneous solution should be removed by rinsing with exceed hot water. Hair can then be washed with a gentle shampoo. In order to avoid contact of the eyes to any residues of the solution during washing, the eyes should be kept closed of the head should be tilted backwards.

2.7. Overdose - Management

It is very rare salicylic acid plasma levels to exceed 5μg/ml during topical application and no toxicity is expected. Induction of toxic symptoms may occur if absorbed concentration exceeds 300μg/ml. Early symptoms are tinnitus with or without loss of hearing, nose bleeding, nausea, vomiting, mucosal sensitivity and dryness. In such cases the treatment should be discontinued immediately.

Poison Center Athens, Tel: +30 210 7793777.

2.8. Possible side effects

a) Most common side effects reported are: burning sensation (40%) and itching (16%), ακολουθούμενα από dryness (2%) and reduction of scalp elasticity (2%).
b) During a 4-week, randomized, double-blind, comparative, multicenter study, which took place during 1993, 50 patients were treated with reference product and 51 patients were treated with Salicylic acid cutaneous solution 10%. The side effects that were reported were:

   Very common (>1/10): Stinging, itching.

   Common (>1/100, <1/10): Dryness, reduced scalp elasticity.

c) The side effects of burning sensation and itching may start within 10 minutes of administration of **Salicylic/Target®** and last 1-2 hours. Usually such reactions are mild and only 4% were characterized as serious.
   If burning sensation persists for longer intervals, the duration of the solution application should be decreased. Εάν υπάρχει παρατεταμένο και έντονο αίσθημα καύσου, πρέπει να μειωθεί ο χρόνος επαφής. Normally the effect is eliminated within few days and the treatment may be continued.
d) It is possible rare cases of contact allergy to salicylic acid or any of the excipients to occur.

If you get any side effect, please talk to your doctor or pharmacist or any other healthcare provider or directly to National Medicine Agency (284 Mesogeion Av., 15562, Cholargos, www.eof.gr).

2.9 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.

2.10 Special warnings about the storage of the product

Store at temperature below 25ºC.

2.11 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 medicine is subjected to medicinal prescription.