PACKAGE LEAFLET: INFORMATION OF THE USER

Budesonide/Target® 0.025% w/w cream,
Budesonide

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

1.1 Trade name

Budesonide/Target®

1.2 Composition

Active substance: Budesonide
Excipients: White paraffin soft, Liquid paraffin, Cetostearyl alcohol, Cetomacrogol 1000, Sorbic acid, Citric acid monohydrate, Sodium citrate anhydrous, Water purified.

1.3 Pharmaceutical form:

Cream

1.4 Quantitative composition:

Each g of cream contains 0.25 mg Budesonide.

1.5 Nature and contents of the container

Each carton of **Budesonide/Target®** cream contains one aluminum tube of 50 g, with screwed plastic cap.

1.6 Pharmacotherapeutic category

Corticosteroid for topical external use (ATC: D07AC09)

1.7 Marketing Authorization Holder

TARGET PHARMA
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:

HELP ABEE,
10 Valaoritou st.,144 52 – Metamorfosi Attikis, Greece
Tel. +30 210.2815353, 210.2843479.

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

2.1 General information

Budesonide/Target® is a medicine that belongs in the class of corticosteroids and is used for external topical use. It has anti-inflammatory, anti-pruritus and vasoconstructive properties. It is applied topically in the affected area.

Budesonide/Target® is indicated for surface skin lesions, which are not caused by microorganisms and are sensitive to corticosteroids, but do not adequately respond to milder formulations. Such lesions include: common psoriasis, lichen lichen, sclerosing atrophic lichen, palmar and plant phlectinosis (ADREWS-BARBER syndrom).

In order to achieve better therapeutic results, coverage of the affected area is needed. **Budesonide/Target®** is indicated for the treatment of severe or refractory to eczema cases. It should be replaced with less potent steroids immediately after the improvement of most severe symptoms.

2.2 Therapeutic Indications

Dermatopathies requiring strong topical corticosteroids:
• Psoriasis (other forms than plaque, palm-feet or reverse psoriasis)
• Atopic eczema
• Nummular eczema
• Contact dermatitis
• Mastocytosis
• Lupus erythematosus
• Parapsoriasis
• Gyroid alopecia

2.3 Contraindications

Hypersensitivity to any of the excipients of the product.
Topical corticosteroid preparations should not be used in cases of undiagnosed dermatitis. Also, the use should be avoided in acne, perioral dermatitis, ulcerative ulcers, and burns as the healing may be delayed.

2.4 Special warnings and precautions for use

2.4.1. General

a. Long-term treatment to children should be avoided. Children are more susceptible to corticosteroid systemic effects, due to increased drug absorption, as the ratio of skin surface and body weight is higher than in adults.
b. If the application will be covered, it is recommended to clean the skin thoroughly in order to avoid infections.
c. Topical corticosteroids should not be used for more than three weeks without re-evaluation by a dermatologist.
d. After repeated use of at least 10-15 days, a temporary decrease or loss of corticosteroid activity

may be observed, due to tachyphylaxis. This phenomenon will be re-stored after discontinuation of the drug for few days or weeks.

e. Use in psoriasis should be with caution and under medicinal supervision, as after the initial benefit, in long term treatments there is a risk of relapse.
f. Due to possible side effects due to extensive absorption, caution is needed if the product is used in large areas or for long term treatment, especially in children and in patients with severe kidney impairment, or prone to bleeding and at imminent vaccinations
g. In general it should be used the less potent corticosteroid that is effective in the indication to be treated. If this is not effective then a more potent corticosteroid may be used.
h. If used near the eyes for long term treatments caution is needed as it may induce cataract or glaucoma. If used on eyelids caution is needed as the medicine should not get in contact with eye-bulb.

2.4.2. Pregnancy

There is not enough evidence on the safety of topical corticosteroids used during pregnancy. Topical application of potent corticosteroids in pregnant animals caused abnormalities in the embryo development. For this reason, topical corticosteroids may be used during pregnancy only if the expected benefit from the treatment is higher than the risk for the embryo. In such case the treatment should not be in high doses or for long time.

2.4.3. Lactation

When the use of a topical corticosteroid is needed during lactation, the recommended dose and the time of treatment should be minimum.

2.4.4. Elderly

Elderly patients that have skin atrophy may be more prone to skin reaction or side effects.

2.4.5. Effects on the ability to drive and use of machines

None known.

2.5 Interactions with other medicines or substances

None known.

2.6 Posology

Apply a small quantity of **Budesonide/Target®** cream to the affected skin area, once or twice daily. Intermittent treatment is recommended. If it is necessary patches may be applied. Generally, no more than 30-60 g of cream per week should be used.

Administration of the product with a watertight dressing may be applied in cases of resisting skin lesions such as thick psoriatic plaques of the elbows and the knees.

The required quantity for topical administration of corticosteroid cream, for use twice a day for one week for an adult man is:

Face and neck:	10g
Trunk (front and rear surface):	60g
Each upper acroteria (except for the extreme hand):	15g
Each lower acroteria (except for the extreme leg):	30g
Extreme hands and legs:	10g

2.7 Overdose - Management

Overdose may be accompanied by topical or systemic symptoms, related to corticosteroid overdose. If overdose symptoms occur, treatment should not be discontinued immediately, dose should be reduced gradually. Adrenal insufficiency may need treatment with intravenous hydrocortisone. it should be noted that overdose with this corticosteroid is unlike to happen unless prolonged and poor use of the product occurs.

In case you receive overdose of the product you should seek advice from your doctor or pharmacist or call at **Poison Center Athens Tel.: +30 210 7793 777.**

2.8 Possible side effects

Topical after prolonged topical use

Topical side effects reported with potent topical corticosteroids at the site of administration are:

Burning sensation, itching, irritation, dryness, folliculitis, depigmentation, thinning of the skin, telangiectasia.
Modified clinical status on misuse (mycoses, scabies), secondary infection, topical microbial infections (new latent infection or worsening of current), fungal infections, facilitating the onset of infectious endemic and acute warts. Inhibition of wound healing, acneic elements, pustules, heat spots, perioral dermatitis, rash in the form of rosacea, relapse of vesicular psoriasis upon discontinuation of treatment (rebound effect), scar-like skin atrophy, linear striations, spider veins, porphyria rashes, diffuse erythema, blistering bullae atypical rashes, allergic hypersensitivity, topical polytrichia. If symptoms of hypersensitivity occur, treatment should be stopped immediately. These side effects are not common but may occur more frequently when watertight dressing is applied or after prolonged treatment.

General after prolonged topical use

Suppression of the coronary-adrenal axis function, reduced cortisol plasma levels – CUSHING syndrome.

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

Use **Budesonide/Target®**, according to your doctor's instructions.
If you forget to use your medicine, do not use the forgotten dosage; continue your treatment as planned.

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 **Budesonide/Target®** at temperature below 25°C.
Keep out of reach and sight of children.

2.12 Date of last revision of this leaflet

23 January 2014

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.