PACKAGE LEAFLET: INFORMATION OF THE USER

Mometasone/Target®
0,1% w/w cream & 0,1% w/w cutaneous solution
Mometasone furoate

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

1.1. Trade name

Mometasone/Target®

1.2. Composition

Active substance: Mometasone furoate.
Excipients:
a) Cream: White soft paraffin, White beeswax, Propylene glycol monostearate, Stearyl alcohol και Ceteareth-20, Hexylene glycol, Aluminium starch octenylsuccinate, Titanium dioxide CI 77891 E171, Phosphoric acid, Water purified.
b) Cutaneous solution: Isopropanol, Propylene glycol, Hyprolose, Sodium phosphate monobasic monohydrate, Phosphoric acid, Water purified.

1.3. Pharmaceutical form

a) Cream.
b) Cutaneous solution.

1.4. Quantitative composition

a) Each g of cream contains 1 mg Mometasone furoate.
β) Each ml of cutaneous solution contains 1 mg Mometasone furoate.

1.5. Nature and contaents of the container

a) Cream: each carton contains one aluminum tube of 15 g or 25 g and a leaflet.
β) Cutaneous solution: Each carton contains a vial of 20 ml or 30 ml and a leaflet.

1.6. Pharmacotherapeutic category

Corticosteroid (ATC: D07AC13).

1.7. Marketing Authorization Holder

ΤΑΡΓΚΕΤ ΦΑΡΜΑ, 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:

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

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

2.1. General information

Mometasone furoate is a synthetic corticosteroid with anti-inflammatory, anti-pruritic and vasoconstructive properties.

2.2. Indications

Mometasone/Target® (cream and cutaneous solution) is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatitis, such as psoriasis and atopic dermatitis.
Mometasone/Target® cutaneous solution may also be used on the scalp.

2.3. Contraindications

Mometasone/Target® (cream and cutaneous solution) should not be used in patients that are hypersensitive to mometasone furoate, other corticosteroids or any of the excipients of these products.
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

If during the treatment irritation or sensitization occurs, discontinuation is needed and treatment should be concluded with a suitable product. Use of these preparations under occlusion should be avoided.
In cases of co-current infection the suitable antifungal agent or antibiotic should be used. If positive response to the treatment does not occur soon, corticosteroid should be discontinued until the infection is properly controlled.
Any of the adverse events reported during systematic administration of corticosteroids, including adrenal suppression, may occur during topical administration especially to infants and children.

Percutaneous absorption of topical corticosteroids will be increased in cases of treatment of extended skin areas or if occlusion is used. In such cases or if prolonged treatment is recommended, caution is needed especially for infants and children. Since pediatric patients present a higher ratio of body surface vs. body weight, they are at higher risk than adults to present suppression of the HPA axis and Cushing's syndrome induced by corticosteroids.
Use of topical corticosteroids in children should be limited to the minimum that provides therapeutic result. Long-term corticosteroid treatment may affect the growth of the child.
Mometasone/Target® cream and cutaneous solution are not intended for ophlalmic use.

2.4.2 Pregnancy

Safety of corticosteroids during pregnancy has not been established. Corticosteroids may be used during pregnancy only if the expected benefit overweighs the potential risk for fetus. Medicines of this category should not be used in maximum dosages or for prolonged treatment in pregnant women.

2.4.3 Lactation

It is not known whether topical use of corticosteroids may result to a systemic absorption that traces of the medicine may be detected to breast milk. Systemically administered corticosteroids are excreted to breast

milk in levels that are not possibly harmful to infant. However discontinuation of lactation or corticosteroid treatment should be considered based on the expected benefit of the medicine to the mother.

2.4.4 Children

Pediatric patients have an increased ratio of body surface versus body weight. Due to this fact children are at higher risk than adults to present suppression of HPA axis or Cushing's syndrome induces by corticosteroid use.
Administration of topical corticosteroids to children should be limited to the minimum effective dose. Prolonged corticosteroid treatment may affect children growth.

2.4.5 Effect on the ability to drive and use of machines

None known.

2.4.6 Special warnings about the excipients

The product should not be used in patients who have previously presented sensitivity to any of the excipients.

2.5 Interactions with other medicines or substances

None known.

2.6 Posology

A thin layer of **Mometasone/Target®** cream should be applied in the affected area once daily.

Few drops (4-6) of **Mometasone/Target®** cutaneous solution should be applied to the affected areas of the skin or the scalp once daily. Gently massage the area until the product is fully absorbed.

2.7 Overdose - management

Symptoms: Extended long-term corticosteroid treatment may suppress coronary-adrenal function resulting to secondary coronary-adrenal insufficiency.

Management: Symptomatic treatment is indicated. Acute hypercorticoid symptoms are reversible. Use of electrolyte solution is recommended if needed. In cases of chronic toxicity, gradual discontinuation of corticosteroid treatment is recommended.

Poison Center Athens Tel.: +30 210 7793777

2.8 Possible side effects

Local adverse reactions that very rarely have been reported with cream include: paraesthesia, pruritus and skin atrophy.

Local adverse reactions that rarely have been reported with cutaneous solution include: burning sensation, folliculitis, acne-like eruptions, pruritus and skin atrophy.

Adverse events rarely reported during treatment with topical corticosteroids include: irritation, hypertrichosis, depigmentation, perioral dermatitis, contact dermatitis, skin atrophy, secondary infection, skin striae and heat rash.

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 25ºC.

2.10 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.