SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Mometasone ABR 1 mg/g cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance in 1 g cream: mometasone furoate of 1 mg.

Excipient(s) with known effect: stearyl alcohol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream
Appearance: white to almost white, homogeneous, creamy mass.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The product is indicated for the treatment of symptoms of inflammation and pruritus in psoriasis (excluding disseminated psoriatic plaques) and atopic dermatitis in adults and children.

4.2 Posology and method of administration

Posology

Adults and elderly (over 65 years)
A thin layer of the cream is applied once daily on the affected skin areas.

Upon application of the product on the skin of the face, the minimum effective therapeutic dose should be used and the duration of treatment should be no longer than 5 days.

Children
The treatment with the product should be carried out at the minimum effective therapeutic dose and the duration should be no longer than 5 days.

Patients with impaired renal and/or hepatic function
No adjustment of the recommended dose is required.

Method of administration
The cream is applied as a thin layer to the affected skin areas. Placement of an occlusive dressing should be an exception, especially in children. Baby diapers may have a similar effect.

4.3 Contraindications

- Hypersensitivity to mometasone or to any of the excipients listed in section 6.1;
- Hypersensitivity to any other corticosteroid products;
- Bacterial (impetigo, cutaneous tuberculosis, syphilis, etc.), viral (herpes simplex, herpes zoster, varicella, etc.) or fungal (dermatophytosis, candidiasis) skin infection;
- Skin reactions following vaccination;
- Rosacea affecting the face;

- Acne vulgaris;
- Perioral dermatitis;
- Perianal or genital pruritus.

4.4 Special warnings and precautions for use

Upon appearance of irritation, pruritus or increased sensitivity, the use of the product should be discontinued and other appropriate treatment should be considered.

Development of an infection requires the inclusion of an appropriate antibacterial or antifungal product in the therapeutic regimen. In the absence of a rapid effect or upon generalisation of the infection, the treatment with the product should be discontinued until the infection is managed. The use of occlusive dressings favours the development of infection in the affected skin areas.

Prolonged and intensive treatment with highly active corticosteroid products may cause local atrophic changes in the skin and dilation of the superficial blood vessels; this should be taken into consideration upon long-term use of the product on skin surfaces, located in the facial area.

Prolonged use of topical corticosteroid products, their application at high doses or over large skin areas can result in significant systemic absorption, which may cause suppression of the hypothalamic-pituitary-adrenal system with the development of clinical symptoms of hypercorticoidism. These manifestations are more common in young children or with the frequent use of occlusive dressings (diapers may have a similar effect). In these cases, limited duration of treatment (up to 5 days) is required.

The use of topical corticosteroid products may lead to chronification of the disease, development of tolerance, increased risk of generalised pustular psoriasis and development of local or systemic toxicity, due to the impaired barrier function of the skin; therefore, the use of the product requires periodic monitoring of the condition.

Treatment with highly potent corticosteroids, including mometasone, should not be discontinued abruptly. Upon prolonged treatment, a rebound phenomenon may develop, presenting with increased intensity of redness, occurrence of burning, stinging. This effect can be avoided by slowly reducing the applied dose or frequency of administrations to complete discontinuation of the treatment.

Corticosteroids may cause changes in the type of skin lesions that may mask certain clinical symptoms and lead to incorrect diagnosis and treatment.

The product should be used with caution in the eye region and its getting into the eyes should be avoided, since this may cause the development of glaucoma.

Mometasone ABR 1 mg/g cream contains as an excipient stearyl alcohol, which may cause local skin reactions, for example contact dermatitis.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy

The administration of topical corticosteroid products in animals may lead to abnormalities in the foetus, but conclusive data on the relationship between the use of these medicines and teratogenic effects in humans are unknown.

However, prolonged use of the product, especially on large skin areas in pregnant women should be avoided and should be done with caution, only after careful assessment of the benefit for the mother/risk for the foetus/newborn.

Breast-feeding
The safety of the product has not been established in relation to the newborn/breast-fed child and therefore, its use during breast-feeding should be done with caution and only after careful assessment of the benefit for the mother/risk for the breast-fed child.

4.7 Effects on ability to drive and use machines

Mometasone ABR 1 mg/g cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

In this section, the following convention has been used for classification of undesirable effects, depending on their frequency:

- Common: ≥1/100 to <1/10
- Uncommon: ≥1/1,000 to <1/100,
- Rare: ≥1/10,000 to <1/1,000 and
- Very rare: <1/10,000
- Not known

Infections and infestations
Very rare: folliculitis
Not known: infections, furunculosis

Nervous system disorders
Very rare: burning sensation at the administration site
Not known: paraesthesia

Skin and subcutaneous tissue disorders
Very rare: pruritus
Not known: contact dermatitis, atrophic skin changes, appearance of striae, especially when occlusive dressings are used and applied on the skin folds, skin hypopigmentation, hypertrichosis.

General disorders and administration site conditions
Not known: pain and other reactions at the administration site

Endocrine disorders
Hypercorticoidism.

Local undesirable effects, reported uncommonly with corticosteroid products, include dryness, irritation, dermatitis, perioral dermatitis, skin maceration, telangiectases and milia.

Paediatric population
Suppression of the hypothalamic-pituitary-adrenal system with the development of clinical symptoms of hypercorticoidism and Cushing's syndrome is more common in children, due to the greater skin surface/body weight ratio.

Chronic administration of corticosteroids may affect the growth and development in children.

4.9 Overdose

Acute overdosage with the local application of corticosteroid products for topical use is unlikely.

With the chronic, continuous use on large skin surfaces or misuse, symptoms of hypercorticoidism may occur. In these cases, gradual discontinuation of the product under medical supervision is required for possible symptoms of adrenal insufficiency. The treatment is symptomatic.

In the event of accidental ingestion of the tube contents, the treatment should be identical to that of overdosage with corticosteroid products intended for oral use.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, dermatological products, potent corticosteroids (III group), ATC code: D07A C13

Pharmacodynamic effects

Upon topical administration, mometasone has rapid, continuous and pronounced anti-inflammatory, antipruritic and vasopressive effects.

Data from animal studies have shown that mometasone is equipotent to a single dose of betamethasone valerate and about 8 times more potent after five applications.

5.2 Pharmacokinetic properties

The extent of absorption through the skin is determined by the quality and composition of the vehicle, the integrity of the epidermis and the presence of an occlusive dressing. Topical corticosteroids are also absorbed through the intact skin. Inflammatory and other disease processes, particularly the presence of atrophic skin changes, favour the absorption of the product.

Following topical application to the skin, the systemic absorption of mometasone is minimal, approximately 0.4% of the dose administered, as the main portion is excreted within 72 hours after administration.

Once entering the systemic blood circulation, topical corticosteroids have pharmacokinetic behaviour similar to the products intended for systemic use. They bind plasma proteins and are metabolised mainly in the liver. The major route of elimination is renal.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hexylene glycol
Purified water
Beeswax, white
Propylene glycol monopalmitostearate
Stearyl alcohol ceteareth 20
Titanium dioxide
Aluminium starch octenylsuccinate
Paraffin, white soft

Phosphoric acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two (2) years

6.4 Special precautions for storage

Store below 25ºC.
Do not freeze.
Keep out of the sight and reach of children.

6.5 Nature and contents of container

Mometasone ABR 1 mg/g cream of 15 g in aluminium tube.
One tube with a package leaflet in a carton box.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Antibiotic-Razgrad AD

Office 201, 68 “Aprilsko vastanie” Blvd

Razgrad 7200, Bulgaria

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

12/2011