SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MOMECON® 0.1% Lotion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each gram of lotion contains 1 mg of mometasone furoate.

Excipients:
Propylene glycol 280 mg
For the list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lotion
Colorless clear liquid.

4. CLINICAL PROPERTIES

4.1. Therapeutic indications
MOMECON is used to eliminate the symptoms of dermatoses that respond to corticosteroids with inflammation and itching. It is indicated for the treatment of psoriasis (psoriasis) and seborrheic dermatitis lesions in the scalp and other hairy areas.

4.2. Posology and method of administration

Posology:
Frequency and duration of administration

A few drops should be applied once a day.

Route of administration:
A few drops of MOMECON should be applied to the diseased skin area, including the scalp areas, and rubbed gently until absorbed through the skin. For the most effective and economical use, hold the nozzle of the bottle close to the affected areas and apply a trace quantity.

Additional information on special populations
Renal/hepatic insufficiency:
Safety and efficacy of mometasone furoate have not been investigated in patients with renal/hepatic impairment.

Pediatric population:
Children have a higher body surface area to body mass ratio compared to adults. Therefore, children are more susceptible to the systemic effects of topical corticosteroids.

The use of topical corticosteroids in children or on the face should be limited to the minimum amount compatible with the effective treatment regimen and the duration of treatment should not exceed 5 days. Chronic corticosteroid therapy may interfere with growth and development.

It is not recommended for use in infants and young children unless it is mandatory.

Geriatric population:
The safety and efficacy of mometasone furoate have not been established in elderly patients.

4.3. Contraindications

Mometasone furoate is contraindicated in bacterial (e.g. impetigo,), viral (e.g. herpes simplex, herpes zoster, chickenpox), and fungal (e.g. candida or dermatophyte) infections.

MOMECON should not be used in patients who are sensitive to mometasone furoate or to other corticosteroids.

4.4. Special warnings and precautions for use

FOR DERMATOLOGICAL USE ONLY. NOT FOR OPHTHALMIC USE.

Systemic absorption of topical corticosteroids may lead to reversible hypothalamus-pituitary-adrenal cortex axis suppression, signs of Cushing's syndrome, hyperglycemia, and glucosuria.

Any of the side effects that are reported following systemic corticosteroid use, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.
Strong steroid use, application to large areas, long-term use, application to areas where the epidermis integrity is impaired and use with closed dressing technique can be considered among the factors that increase systemic absorption.

Systemic absorption of topical corticosteroids will increase when treatment is applied to large body areas or closed dressing technique is applied. Under these conditions or if long-term use is envisaged, appropriate measures should be taken, especially infants and children.

After discontinuation of the drug, the function of the hypothalamus-pituitary-adrenal axis improves rapidly. Rarely, symptoms related to discontinuation of steroid use may occur. In such cases, systemic corticosteroid replacement therapy may be administered.

In cases where skin irritation is observed during administration, the drug should be discontinued.

If irritation or sensitization develop during MOMECON treatment, treatment should be discontinued, and appropriate therapy should be instituted. Should an infection develop, an appropriate antifungal or antibacterial agent should be started. If a favorable response does not occur in a short time, the corticosteroid should be discontinued until the infection is adequately controlled.
Considerations that patients should know:
1. This drug is developed for external use in skin diseases. It should not be in contact with the eyes.
2. It should not be used for any disease other than the disease recommended by the doctor.

3. Do not cover the treated skin area with a bandage or any other dressing unless your doctor recommends.
4. When an unexpected effect is seen, the doctor should be consulted.

MOMECON contains propylene glycol, which can cause skin irritation.

4.5. Interaction with other medicinal products and other forms of interaction

There are no known interactions.

4.6. Pregnancy and lactation

General recommendation
Pregnancy category: C.

Women with child-bearing potential/Birth control (Contraception)
There are no data on the use of MOMECON in women with childbearing potential and who do not use birth control.

Pregnancy
There are no sufficient data on the use of mometasone furoate in pregnant women. Animal studies revealed reproductive toxicity. Potential risk for humans is unknown. MOMECON should not be used during pregnancy unless necessary.

There are no studies showing the teratogenic effects of topical administered corticosteroids in pregnant women. Therefore, such drugs should be used during pregnancy only after careful consideration of the benefits/risks. The administration during pregnancy should not be on large surfaces and should not cover long treatment times.

There is limited information on the safety of the use of mometasone furoate in pregnant women. Topical corticosteroids should be used in pregnant women only if the potential benefit justifies the potential risk to the fetus. Drugs included in this class should not be used in pregnant women in large quantities and for a long time.

Lactation period
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. MOMECON should be administered to nursing mothers only after careful consideration of the benefit/risk relationship.

Reproductive ability/Fertility:
Genetic toxicity studies (Ames test, mouse lymphoma test, and micronucleus test) with Mometasone furoate did not show any mutagenic potential.

4.7. Effects on the ability to drive and use machines

The product has no influence on the ability to drive and use machines.

4.8. Undesirable effects

Frequencies are defined as: Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), unknown (not estimated by available data).

Skin and subcutaneous tissue disorders
Rare:
Local adverse reactions such as irritation, hypertrichosis, hypopigmentation, perioral pigmentation, allergic contact dermatitis, skin maceration, secondary infection, stria, and miliaria may be seen.

Very rare:
Local adverse reactions such as paresthesia, pruritus and skin atrophy, abscess, burning, exacerbation of the disease, dry skin, erythema, furunculosis, and acne may be seen.

4.9. Overdose and treatment

When logical corticosteroids are overdosed, they may cause systemic side effects as a result of absorption.

Excessive prolonged use of topical corticosteroids may suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency. In this case, treatment should be stopped.

In case of overdose, symptomatic treatment should be administered. Acute hypercorticoid symptoms are almost completely reversible. If necessary, electrolyte imbalance is treated. In cases of chronic toxicity, corticosteroids are recommended to be discontinued gradually.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Dermatological preparations, Potent corticosteroids (Group III)
ATC code: D07AC13

Mometasone furoate is a corticosteroid with a pronounced anti-inflammatory, antipruritic, and antipsoriatic effect.

Corticosteroids are steroid hormones secreted from the kidney and their synthetic analogs. They are used in pharmacological doses to provide an anti-inflammatory effect or to suppress immunity.
Topical corticosteroids may be absorbed through normal and damaged skin. The rate of absorption from the skin varies according to the excipient used in the preparation, the integrity of the epidermis, and the application of closed dressings. In cases of skin inflammation and closed dressings of the treated area, absorption increases through the skin.

The effects of mometasone furoate lotion applied to the diseased skin on the hypothalamus-pituitary-surrenal axis were investigated and plasma cortisol levels were found to be not changed significantly.

5.2. Pharmacokinetic properties

General properties
Absorption: The systemic absorption following topical application of mometasone furoate lotion 0.1% is minimal, approximately 0.4% of the applied dose in man.

Distribution: After the absorption of the topical corticosteroids through the skin, they undergo the same pharmacokinetic processes as the systemic corticosteroids and bind to plasma proteins at varying levels.

Biotransformation: They are mainly metabolized in the liver.

Elimination: Mometasone furoate is excreted through the kidneys, some topical steroids and their metabolites are also excreted via bile.

5.3. Preclinical safety data

Genetic toxicity studies (Ames test, mouse lymphoma test, and micronucleus test) with Mometasone furoate did not show any mutagenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Isopropyl alcohol
Propylene glycol
Hydroxypropyl cellulose
Sodium dihydrogen phosphate monohydrate
Phosphoric acid (pH adjuster)
Purified water

6.2. Incompatibilities

No known incompatibility.

6.3. Shelf-life

36 months

6.4. Special precautions for storage

Store at room temperature below 30°C.

6.5. Nature and contents of the container

It is presented in a 30 mL HDPE bottle with its mouth drip, locked with HDPE cap, along with a patient information leaflet in a cardboard box.

7. MARKETING AUTHORIZATION HOLDER

BİLİM İLAÇ SAN. ve TİC. A.Ş.
34440 Beyoğlu-ISTANBUL-TURKEY

8. MARKETING AUTHORIZATION NUMBER

05342/07445/REN/2020

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

Date of renewal of authorization:
Sep 23, 2020

10. DATE OF REVISION OF THE TEXT