SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MOMECON 0.1% pomade

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
1 g MOMECON contains 1 mg mometasone furoate.

Excipients:
Propylene glycol stearate 30 mg

For the list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pomade
Homogeneous, white pomade with a slight wax odor.

4. CLINICAL PROPERTIES

4.1. Therapeutic indications

MOMECON is used to treat inflammatory and pruritic lesions of psoriasis, eczematous dermatitis (such as atopic dermatitis) and all other dermatoses that respond to corticosteroids.

4.2. Posology and method of administration

Posology/Frequency and duration of administration
Route of administration:
MOMECON should be applied to the affected skin areas as a thin layer.

Frequency and duration of administration
It should be applied once a day.

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

Pediatric population:
Children have a greater ratio of skin surface to body mass 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.

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

4.3. Contraindications

MOMECON should not be used in patients with hypersensitivity to any of the excipients of the mometasone furoate preparation and other topical corticosteroids.

Mometasone furoate is contraindicated in facial rosacea, acne vulgaris, perioral dermatitis, perianal and genital pruritis, napkin eruptions, bacterial (e.g. impetigo, pyodermas), viral (e.g. herpes simplex, herpes zoster, chickenpox), and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or post-vaccine reactions. 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

If irritation or sensitization develop during MOMECON treatment, treatment should be discontinued and appropriate therapy 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.

Local and systemic toxicity may be observed in long-term treatments and closed dressing applications, especially on damaged large skin surfaces, intertriginous skin areas If used in childhood, or on the face, the treatment should be limited to 5 days and occlusion should not be used. Long term continuous therapy should be avoided in all patients irrespective of age.

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

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.

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.

Pediatric patients may be more susceptible to topical corticosteroid-induced HPA axis suppression and Cushing syndrome than adult patients; because the skin surface area to body mass ratio is greater. The use of topical corticosteroids in children should be limited to the lowest amount that will make the treatment effective. Chronic corticosteroid therapy may interfere with the growth and development of the children

MOMECON is not intended for ophthalmic use.

Considerations that patients should know:
1. This drug is developed for external use in skin diseases. Avoid 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.

MOMECON contains propylene glycol stearate which may cause irritation in the skin.

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:
Pregnancy category is 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 MOMECON 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 locally 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 MOMECON 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 established 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.

CONSULT YOUR PHYSICIAN IF ANY UNEXPECTED EFFECT OCCURS.

4.9. Overdose and treatment

Overdose due to the use of MOMECON has not been reported.

Excessive prolonged use of topical corticosteroids may suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency.

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.

When topical corticosteroids are overdosed, they may cause systemic side effects as a result of absorption. In this case, treatment should be stopped.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Potent corticosteroids
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 are effective in the treatment of dermatoses that respond to corticosteroids due to their anti-inflammatory and antipruritic properties.

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.

5.2. Pharmacokinetic properties

General properties

Absorption:

The systemic absorption following topical application of mometasone furoate pomade 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:

It is partially metabolized in the liver.

Elimination:

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

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

5.3. 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

Hexylene glycol
White wax (beeswax)
White petrolatum
Propylene glycol stearate
Phosphoric acid(pH regulator)
Purified water

6.2. Incompatibilities

No known incompatibility.

6.3. Shelf-life

24 months

6.4. Special precautions for storage

Store at room temperature below 30°C. Do not freeze.

6.5. Nature and contents of the container

It is packed in a lacquered aluminum tube with HDPE screw cap in packages of 30 grams along with a patient information leaflet in a cardboard box.

6.6. Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with "Regulation on Control of Medical Waste" and "Regulation on Control of Packaging and Packaging Wastes".

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER

05343/07446/REN/2020

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

Date of first authorization:
Date of renewal of authorization: Sep 23, 2020

10. DATE OF REVISION OF THE TEXT