SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Ovixan 1 mg/g cutaneous solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram cutaneous solution contains 1 mg mometasone furoate

Excipients with known effect

300 mg propylene glycol per gram solution.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous solution
Colourless to slightly yellow low-viscous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ovixan is indicated for the symptomatic treatment of inflammatory skin conditions which respond to topical treatment with glucocorticosteroids, such as atopic dermatitis and psoriasis (excluding widespread plaque psoriasis).

4.2 Posology and method of administration

Posology

Adults (including older people) and children (from 6 years):
Ovixan is applied in a thin film once daily on the affected areas of skin. The application frequency is then gradually decreased. Use of a less potent corticosteroid is often preferred when clinical improvement is achieved.

Ovixan cutaneous solution is intended for treatment of skin lesions on the scalp but it may also be used on other parts of the body.

As for all strong topical glucocorticoids Ovixan should not be applied on the face other than under close supervision by a doctor.

Ovixan should not be used for long periods (over 3 weeks) or on large areas (over 20% of body surface area). In children a maximum of 10% of body surface area should be treated.

Paediatric population
Children below 6 years:
Ovixan is a strong glucocorticoid (group III) and it is usually not recommended for children below 6 years since relevant safety data are lacking (see section 4.4).

Method of administration

Topical use.

4.3 Contraindications

Hypersensitivity to the active substance, to other corticosteroids or to any of the excipients listed in section 6.1.

Ovixan is contraindicated for patients with facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritus, napkin eruptions, bacterial infections (e.g. impetigo), viral infections (e.g. herpes simplex, herpes zoster and chickenpox) and fungal infections (e.g. candida or dermatophyte), varicella, tuberculosis, syphilis or post-vaccine reactions. Ovixan should not be used on wounds or on skin which is ulcerated.

4.4 Special warnings and precautions for use

If irritation or sensitisation develops with the use of Ovixan, treatment should be withdrawn and appropriate therapy instituted.

Ovixan cutaneous solution contains propylene glycol that may cause skin irritation.

Glucocorticoids can change the appearance of some lesions and make it difficult to establish an adequate diagnosis and can also delay the healing.

Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled.

Systemic absorption
Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying a topical steroid to a large surface area or areas under occlusion should be evaluated periodically for evidence of HPA axis suppression.

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin, in flexures and with polythene occlusion. If used on the face, occlusion should not be used. If used on the face, courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age.

Psoriasis
Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of centralised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important.

Treatment discontinuation
As with all potent topical glucocorticosteroids, avoid sudden discontinuation of treatment. When long term topical treatment with potent glucocorticoids is stopped, a rebound phenomenon can develop which takes the form of a dermatitis with intense redness, stinging and burning. This can be prevented by slow reduction of the treatment, for instance continue treatment on an intermittent basis before discontinuing treatment.

Visual disturbance
Ovixan should not be applied to the eyelids because of the potential risk of glaucoma simplex or subcapsular cataract. Ovixan topical preparations are not for ophthalmic use.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSR) which have been reported after use of systemic and topical corticosteroids.

Paediatric population
Use with care in children. The side effects that have been reported during systemic use of corticosteroids, including inhibition of adrenal cortex, may also appear with local use of corticosteroids, especially in children. Children may be more sensitive to the influence of topical glucocorticoids on the hypothalamic-pituitary- adrenal system (HPA-axis) and to Cushing's syndrome than adults because the skin surface is larger in relation to the body weight. Chronic treatment with glucocorticoids may influence the growth and development in children (see section 4.8).

Treatment with occlusive dressing should not be used in the childhood.

As the safety and efficacy of mometasone furoate in paediatric patients below 2 years of age have not been established, Ovixan is not recommended in this age group.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
Corticosteroids passes the placenta. There are no clinical data from the use of mometasone furoate during pregnancy. Studies of mometasone furoate in animals following oral administration have shown teratogenic effects, see section 5.3. The potential risk for humans is unknown. Although systemic exposure is limited, Ovixan should only be used during pregnancy after careful consideration of risks and benefit.
During pregnancy corticosteroids with low potency should be prescribed for treatment of larger body surfaces during longer periods.

Breast-feeding
It has not been established if mometasone furoate passes over to maternal milk. Mometasone furoate should only be given to lactating mothers after careful consideration of risk and benefit. Ovixan should not be applied to the breast or adjacent skin during lactation.

Fertility
No known effects.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The adverse events are presented according to MedRA system organ classification within each frequency area and after decreasing degree of severity:
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)
Not known (cannot be estimated from the available data)

Adverse events that have been reported during use of glucocorticoids for topical use include:

Treatment related adverse events reported according to system organ classification and frequency	
Infections and infestations	
Not known	Secondary infection, furuncolosis
Very rare	Folliculitis
Nervous system disorders	
Not known	Paresthesia
Very rare	Burning sensation
Eye disorders	
Not known	Vision, blurred (see also section 4.4)
Vascular disorders	
Very rare	Telangiectasis
Skin and subcutaneous tissue disorders	
Not known	Allergic contact dermatitis, perioral dermatitis, hypopigmentation, hypertrichosis, striae, maceration of skin, miliaria, acneiform reactions, local skin atrophy, irritation, papulous rosacea like dermatitis (facial skin), capillary sensitivity (ekkymosis), dryness, hypersensitivity (mometasone)
Very rare	Pruritus
General disorders and administration site conditions	
Not known	Application site pain, application site reactions

Increased risk for systemic effects and local adverse events is present with frequent administration, when treating large areas or during long-term as well as during treatment of intertriginous areas or with occlusion. Hypo- or hyper-pigmentation has been reported in rare cases in connection with other cortisone medicines and may therefore appear with mometasone furoate.

Adverse events that have been reported during systemic treatment with glucocorticoids – including adrenal suppression- may also appear with topically applied corticosteroids.

Treatment of widespread psoriasis or sudden stopping of prolonged therapy with a potent corticosteroid may induce pustular or erythrodemic psoriasis.

Flare-up of eczema may be seen as a rebound phenomenon after abrupt stopping of therapy.

Paediatric population
Paediatric patients may demonstrate greater susceptibility to topical glucocorticoid-induced hypothalamic-pituitary-adrenal axis suppression and Cushing's syndrome than mature patients because of a larger skin surface to body weight ratio. Chronic glucocorticoid therapy may interfere with the growth and development of children.
Intracranial hypertension has been reported in paediatric patients receiving topical glucocorticoids. Manifestations of intracranial hypertension include bulging fontanelles, headaches and bilateral papilloedema.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reaction via the national reporting system listed in Appendix V.

4.9 Overdose

Exaggerated long-term use of topical glucocorticosteroids may suppress the HPA-axis function and give rise to secondary adrenal cortex suppression. If suppression of the HPA-axis is reported, the number of applications times should be decreased or treatment should be stopped while observing necessary caution in these situations.

The steroid content of each container is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, Dermatological preparations. Corticosteroids, Plain.
ATC code: D07AC13

Mechanism of action and pharmacodynamic effects
Mometasone furoate is a strong glucocorticoid, group III

The active substance, mometasone furoate, is a synthetic, non-fluorinated glucocorticoid with a furoate esther in position 17.

As for other corticosteroids for topical use mometasone furoate has anti-inflammatory, antipruritic and anti-allergic effects.

5.2 Pharmacokinetic properties

Absorption
Results from percutaneous absorption studies show that the systemic absorption is less than 1 %.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety toxicology, genotoxicity and carcinogenicity (nasal administration) of mometasone furoate besides what is already known for corticosteroids.
Studies of corticosteroids in animals following oral administration have shown reproduction toxicity (cleft palate, skeletal malformations).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Isopropyl alcohol
Hydroxypropylcellulose
Sodium dihydrogen phosphate dihydrate
Phosphoric acid, concentrated (for pH adjustment)
Water, purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

White LDPE bottles of polyethylene with a white LDPE dropper, and a white HDPE, tamper proof screw cap of polyethylene.

Pack sizes:
30 ml, 100 ml, 2 x 100 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

2018-03-09