1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Enclosed

1. Name of the medicinal product

Elicasal (Mometasone Furoate 0.1% w/w, Salicylic acid 5% w/w) ointment.

2. Qualitative and quantitative composition

Each gram of ointment contains 1 mg of mometasone furoate and 50 mg of salicylic acid.
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Ointment

4. Clinical particulars

4.1 Therapeutic indications

Initial treatment of moderate to severe plaque psoriasis.
It is indicated in adults and adolescents 12 years of age and older.

4.2 Posology and method of administration

Posology

Apply a thin layer to the affected skin areas once or twice daily. Maximum daily dose is 15 g, applied to no more than 30% of the body surface. A treatment duration for longer than 3 weeks has not been evaluated within the pivotal studies. As for all potent steroids it is recommended that the applications are gradually tapered down.

Paediatric population

The safety and efficacy of Elicsal in children under 12 years of age have not been established.

Method of Administration

For topical use only

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
As with other topical glucocorticoids, Elicasal ointment is contraindicated in patients with:
– bacterial infection (e.g, pyodermas, syphilis, and tuberculosis),
– viral infection (e.g., herpes simplex, varicella, herpes zoster, *verrucae vulgares*, *condylomata acuminata*, *molluscum contagiosum*)
– fungal infection (dermatophytes and yeasts), and
– parasitical infections if causal therapy is not concomitantly given.

Elicasal Ointment is also contraindicated in patients with postvaccination reactions, perioral dermatitis, rosacea, acne vulgaris, and skin atrophy.

Elicasal is contraindicated in the last trimester of pregnancy (see 4.6).

4.4 Special warnings and precautions for use

As with all cutaneous glucocorticoid preparations, precautions should be taken when extensive body surface areas are treated.

Elicasal is not recommended for use under occlusive dressing. Elicasal is not for use on the face, groin, genital, or other intertriginous areas. Elicasal is not for ophthalmic use. When using Elicasal ointment, care must be taken to avoid contact with the eyes, mucosae and open wounds. Elicasal should not be used on ulcers, wounds, or stretch marks.

Elicasal is not recommended for use in pustular or psoriasis guttata.

If irritation, including excessive dryness, develops Elicasal should be discontinued and appropriate therapy instituted.

Glucocorticoids can mask, activate, or exacerbate skin infection. If concomitant skin infection develops, an appropriate antifungal or antibacterial agent should be used. If a favourable response does not occur, the use of Elicasal should be discontinued until the infection has been adequately controlled.

Salicylic acid may act as a sunscreen agent. Patients who combine cutaneous therapy of Elicasal with UV therapy should remove the remaining ointment and clean the treated area before the start of UV therapy to reduce the photoprotective action, and thereby reduce the risk of burning of the untreated surrounding area to a minimum. Following the UV treatment, the ointment can be reapplied.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in children.

Elicasal contains propylene glycol stearate which may cause skin irritation.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) 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 of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Paediatric use

The safety and efficacy of Elicasal have not been established in children below the age of 12 years.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Pregnancy and lactation

Pregnancy

There are no clinical data from the use of mometasone furoate during pregnancy. Studies of mometasone furoate and salicylic acid in animals have shown teratogenic effects, see section 5.3. The risk for teratogenic effects in human fetus can be considered low due to the topical administration route of the product. Like other glucocorticosteroids, mometasone furoate formulations should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or fetus.

During the first and second trimester:

The safety of Elicasal in pregnant women has not been established. Therefore, the use of Elicasal during the first and second trimester of pregnancy should be avoided.

During the third trimester:

During the third trimester of pregnancy, all prostaglandin synthetase inhibitors including salicylic acid may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy, prolonged bleeding time in both mother and child may occur. Therefore, Elicasal is contraindicated during the last trimester of pregnancy (see 4.3).

Breast-feeding

It is not known whether cutaneous administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Elicasal ointment is therefore not recommended unless clearly necessary.

Fertility

There are no clinical data concerning the effect of mometasone furoate on fertility. Animal studies have shown reproductive toxicity, but no effects on fertility (see section 5.3). There are no data on the effects of salicylic acid on fertility.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Adverse reactions that have been reported with the use of cutaneous corticosteroids include:

Table 1: Treatment-related adverse reactions reported by body system and frequency
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)

System Organ Class	Frequency	Adverse Reactions
Infections and infestations	Uncommon	Infection
Immune system disorders	Rare	Hypersensitivity
Endocrine disorders	Rare	Adrenal suppression.
Eye disorders	Not known	Vision blurred (see also section 4.4)
Skin and subcutaneous tissue disorders	Common Uncommon	Pruritus, local skin atrophy Skin striae, rosacea like dermatitis, ecchymosis, folliculitis

	Rare Not known	Hypertrichosis, skin hypopigmentation Skin irritation, skin maceration, dry skin, dermatitis acneiform, dermatitis, dermatitis contact, skin exfoliation, telangiectasia, miliaria
General disorders and administration site conditions	Common	Application site burning sensation

4.9 Overdose:

Excessive, prolonged use of topical corticosteroids can suppress hypothalamic-pituitary-adrenal-axis function, resulting in secondary adrenal insufficiency. If hypothalamic-pituitary-adrenal-axis suppression is noted, an attempt should be made to reduce the frequency of application or to withdraw the drug, observing the care required in these situations.
In the clinical program doses of more than the recommended maximum daily dose of 15 g/day had a transient effect on the hypothalamic-pituitary-adrenal-axis function.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: corticosteroids, potent, other combinations; ATC-code D07XC03.
Mechanism of action

Like other cutaneous corticosteroids, mometasone furoate has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the cutaneous steroids, in general, is unclear.

Salicylic acid has been shown to desquamate the stratum corneum while not effecting changes in the structure of the viable epidermis. This mechanism of action has been attributed to a dissolution of the intercellular cement substance. Salicylic acid enhances the absorption of mometasone furoate through the skin layers.

Pharmacodynamic effects

The pharmacodynamic activity of Elicasal is directly related to its active components, mometasone furoate and salicylic acid, and its vehicle. Mometasone is a strongly potent glucocorticoid belonging to the EU class III.

Minor effects on the hypothalamic-pituitary-adrenal-axis were observed when up to 7.5 g of Elicasal were applied twice daily at a total daily dose of 15 g for seven days to 30% of the body surface area, as indicated by the occurrence of a single below normal plasma cortisol level in one patient. The value returned to normal during continuation of therapy.

5.2 Pharmacokinetic properties

Absorption

The degree of absorption and systemic effects depends on:

- treated area and condition of the epidermis
- duration of treatment
- application area
- use of occlusive bandage

Following a single cutaneous application of a combination of ^{3}H-mometasone furoate 0.1% and salicylic acid 5% ointment for 12 hours without occlusion, approximately 1.5% of the applied dose was absorbed systemically. Mean peak plasma salicylic acid level was 0.0066 mmol/l. Systemic toxic reactions to salicylic acid are usually associated with much higher plasma levels (2.17 to 2.90 mmol/l).

Following application of up to 7.5 g of Elicasal twice daily without occlusion for 3 weeks, salicylate levels in blood were <0.36 mmol/l, which is the lower limit of detection. The laboratory normal salicylate plasma concentration range seen with oral treatment giving systemic effect is 1-2 mmol/l.

Biotransformation

Absorbed mometasone furoate undergoes rapid and extensive metabolism to multiple metabolites. These are not considered to have pharmacological activity. No major metabolite is formed.

Elimination

Following a single cutaneous application (12 hours) of a combination ointment formulation of ^{3}H-mometasone furoate 0.1% and salicylic acid 5% to patients with psoriasis, approximately 0.36% and 1.11% of the radioactivity was recovered in the urine and faeces, respectively, over a 5-day collection period. Following this same application, the effective half-life of salicylic acid is 2.8 hours.

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 glucocorticoids.

Studies of corticosteroids in animals have shown reproduction toxicity (cleft palate, skeletal malformations).

In reproduction toxicity studies in rats, prolonged gestation and prolonged and difficult labour was detected. Moreover, reduction in offspring survival, in body weight and body weight gain was observed. There was no impairment of fertility.

For salicylic acid, teratogenicity, evident as skeletal and visceral malformations, has been observed in reproduction toxicity studies. There are no other preclinical data of relevance for the safety evaluation besides what has already been considered in the summary of product

characteristics.

6. Pharmaceutical particulars

6.1 List of excipients

White Soft Paraffin (White Petroleum Jelly)

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

36 months

Advice to be used within 3 months of tube opening.

6.4 Special precautions for storage

Do not store above 30°C.

Keep out of reach of children.

6.5 Nature and contents of container

30 gm printed collapsible aluminum tubes, internally lacquered, latex end seal, membrane nozzle, white full dia HDPE cap with spike for piercing. One such Aluminium Tube is packed in a carton along with one Patient Information Leaflet (PIL).

6.6 Special precautions for disposal and other handling

No special requirements.

7.Marketing authorisation holder

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8. Marketing authorisation number(s)

B4-7660

9.Date of first authorisation/renewal of the authorization

13-Oct-17

10.Date of revision of the text

Augest-22