Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Monovo 1 mg/g Cutaneous Emulsion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of cutaneous emulsion contains 1 mg mometasone furoate (0.1% w/w mometasone furoate).
Each drop of the cutaneous emulsion contains 0.05 mg of mometasone furoate.

Excipient with known effect:
30 mg of propylene glycol caprylate per gram cutaneous emulsion

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous emulsion

A white cutaneous emulsion.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Monovo is indicated for the symptomatic treatment of inflammatory skin conditions which respond to topical treatment with corticosteroids, such as atopic dermatitis and psoriasis (excluding widespread plaque psoriasis).
Monovo is indicated for the symptomatic treatment of inflammatory and pruritic diseases of the scalp such as scalp psoriasis.
Monovo is indicated in adults and children above 6 years.

4.2 Posology and method of administration

For application on the skin (cutaneous use).

Adults (including elderly patients) and children aged 6 years and over
Monovo should be applied to the affected skin area (e.g. on the scalp) once daily.
The bottle should be turned upside down and gently squeezed.
10 to 12 drops are enough to cover an area twice the size of an adult hand.
Massage gently and thoroughly until the medication disappears.

Potent topical corticosteroids should not be applied to the face except in special circumstances under close monitoring by the physician.

Monovo 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 the body surface area should be treated. It should not be used occlusively or in intertriginous areas. Use of a weaker corticosteroid is often advisable when there is a clinical improvement.

Children below 6 years
The safety and efficacy of Monovo in children aged below 6 years have not been established (see section 4.8).

4.3 Contraindications

Monovo is contraindicated in patients with:
- Hypersensitivity to the active substance, to other corticosteroids or to any of the excipients listed in section 6.1
- facial rosacea
- acne vulgaris
- skin atrophy
- perioral dermatitis
- perianal and genital pruritus
- napkin eruptions
- bacterial (e.g. impetigo, pyodermas), viral (e.g. herpes simplex, herpes zoster, chickenpox (varicella), verrucae vulgares, condylomata acuminata, molluscum contagiosum) and fungal (e.g. candida or dermatophyte) infections
- parasitical skin infections (e.g. scabies)
- tuberculosis
- syphilis
- post-vaccine reactions
- wounds or skin which is ulcerated

4.4 Special warnings and precautions for use

Monovo should not be used on the eyelids and any contact with the eyes should be avoided.

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

Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted and, particularly if a favorable response does not occur promptly, discontinuation of the corticosteroid should be considered, until the infection is adequately controlled.

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for corticosteroid insufficiency after withdrawal of treatment. Manifestation of Cushing´s syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

Caution should be exercised when large areas of the body are treated and long term continuous therapy should be avoided in all patients irrespective of age, as prolonged use or use on large areas increases the potential for local or systemic adverse effects. Monovo should not be used under occlusion or in intertriginous areas.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound, relapses following development of tolerance, risk of generalized 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.

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

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

Monovo contains propylene glycol caprylate which may cause skin irritation.

<u>Visual disturbance</u>
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 (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
Corticosteroids cross the placenta. After systemic uses of high dose corticosteroids, effects on the foetus/neonate have been described (intra-uterine growth retardation, adrenocortical suppression, cleft palate).

There is very limited data on the use of topical mometasone during pregnancy.

Although systemic exposure to mometasone is limited, Monovo should only be used during pregnancy after careful consideration of the benefit/risk assessment.

Pregnant women should not use the product on larger skin areas for long periods.

Animal studies have shown reproduction toxicity and teratogenicity (see section 5.3). The potential risk for humans is unknown.

Breastfeeding
It is not known whether mometasone furoate is excreted into breast milk. Monovo should be administered to nursing mothers only after careful consideration of the benefit/risk assessment. During the breastfeeding period, Monovo must not be applied in the breast area.

Fertility
No known effects.

4.7 Effects on ability to drive and use machines

Monovo has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions are listed in Table 1 according to MedDRA system organ class and in decreasing frequency defined as follows:
-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 (frequency cannot be estimated from the available data)

Undesirable effects that have been reported in connection with external corticosteroid treatment include:

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

Infections and infestations	
Uncommon	Secondary infection
Immune system disorders	
Uncommon	Allergic contact dermatitis
Eye disorders	
Not known	Vision, blurred (see also section 4.4)
Vascular disorders	
Very rare	Telangiectasias

Skin and subcutaneous tissue disorders	
Common	Mild to moderate burning sensations at the application site, tingling/stinging, pruritus, bacterial infections, paraesthesia, furunculosis, local skin atrophy
Uncommon	Striae, irritation, hypertrichosis, hypopigmentation, perioral dermatitis, maceration of the skin, papulous rosacea-like dermatitis (facial skin), acneiform reactions, capillary brittleness (ecchymoses), miliaria, dryness, sensitisation (mometasone), folliculitis

There is an increased risk of systemic effects and local undesirable effects exists with frequent dosing, treatment of large areas or in the long term and also the treatment of intertriginous areas or with occlusive dressings. Hypopigmentation or hyperpigmentation has been reported in isolated cases (rare) in connection with other corticosteroids and may therefore occur with Monovo.
Those side effects which have been reported with systemic corticosteroids – including adrenal suppression – may also potentially occur with topically applied corticosteroids in some subjects.Allergic (hypersensitivity) reactions have been reported in connection with propylene glycol and frequencies are unknown.

Paediatric population
Paediatric patients may be more susceptible to developing hypothalamic-pituitary-adrenal axis suppression (HPA) and Cushing's syndrome, when treated with topical corticosteroids, than adults due to their larger skin surface to body mass ratios. Chronic corticosteroid therapy may interfere with the growth and development of children.
Intracranial hypertension has been reported in paediatric patients receiving topical corticosteroids. 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 reactions via the HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie , e-mail: medsafety@hpra.ie

4.9 Overdose

Excessive long-term use of topical corticosteroids may suppress HPA-axis function and give rise to secondary adrenocortical insufficiency. If suppression of the HPA-axis is reported, the number of application times should be decreased or treatment should be stopped while observing necessary caution in these situations.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, potent (group III)
ATC Code: D07AC13
Monovo is a potent corticosteroid, group III.

Mechanism of action
The active substance, mometasone furoate, is a synthetic, non-fluorinated corticosteroid with a furoate ester in position 17.

Like other corticosteroids for external use, mometasone furoate exhibits marked anti-inflammatory activity and marked anti-psoriatic activity in standard animal predictive models.

Pharmacodynamic effects
In the croton oil assay in mice, mometasone furoate (ED50 = 0.2 mcg/ear) was equipotent to betamethasone valerate after single application and about 8 times as potent after five applications (ED50 = 0.002 mcg/ear/day versus 0.014 mcg/ear/day).

In guinea pigs, mometasone furoate was approximately twice as potent as betamethasone valerate in reducing M.ovalis-induced epidermal acanthosis (i.e. anti-psoriatic activity) after 14 applications.

5.2 Pharmacokinetic properties

No pharmacokinetic studies have been performed with Monovo.

Results from percutaneous absorption studies have indicated that systemic absorption following topical application of other products containing mometasone furoate 0.1 % is minimal. The results show that less than 1 % of the active ingredient is absorbed by the intact skin in 8 hours (without using an occlusive dressing).

Characterisation of metabolites was not feasible owing to the small amounts present in plasma and excreta.

5.3 Preclinical safety data

Studies of corticosteroids in animals following oral administration have shown reproduction toxicity (cleft palate, skeletal malformations).
There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Liquid paraffin
Hexylene glycol
Octyldodecanol
Medium-chain triglycerides
Macrogol stearyl ether (21)
Macrogol stearyl ether (2)
Diisopropyl adipate
Propylene glycol caprylate
Hard paraffin
Phenoxyethanol
Citric acid
Sodium citrate
Xanthan gum

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years
After first opening: 3 months

6.4 Special precautions for storage

Do not store above 25 °C.
Do not freeze.

6.5 Nature and contents of container

The cutaneous emulsion is filled in HDPE bottles fitted with a blue or white HDPE screw cap with nozzle in a cardboard carton.
Carton of 1 bottle.
Pack sizes: 20 g, 30 g, 50 g, 60 g and 100 g.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Almirall Hermal GmbH
Scholtzstrasse 3
21465 Reinbek
Germany

8 MARKETING AUTHORISATION NUMBER

PA1548/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 March 2012
Date of latest renewal: 12 January 2018

10 DATE OF REVISION OF THE TEXT

November 2019