

AUSTRALIAN PRODUCT INFORMATION

NOVASONE®

(mometasone furoate) Ointment, Lotion and Cream

1 NAME OF THE MEDICINE

Mometasone furoate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mometasone furoate 0.1% (1 mg/g)

For the full list of excipients, see **Section 6.1 List of Excipients**.

3 PHARMACEUTICAL FORM

NOVASONE (mometasone furoate) 0.1% (1 mg/g) is available as ointment, cream, and lotion.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

NOVASONE Cream, Ointment and Lotion are indicated for short-term (up to four (4) continuous weeks) relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, such as psoriasis and atopic dermatitis.

NOVASONE Lotion is also suitable for short-term use for scalp psoriasis and seborrhoeic dermatitis.

4.2 DOSE AND METHOD OF ADMINISTRATION

A thin film of NOVASONE Cream or Ointment should be applied to the affected skin areas once daily. NOVASONE Cream is suitable for moist lesions; the ointment should be used for dry, scaling and fissured lesions.

A few drops of NOVASONE Lotion should be applied to affected skin areas including scalp sites once daily; massage gently and thoroughly until the medication disappears.

4.3 CONTRAINDICATIONS

NOVASONE Cream, Ointment and Lotion are contraindicated in patients who are hypersensitive to mometasone furoate or to other corticosteroids. Like other topical corticosteroids, NOVASONE is contraindicated in most viral infections of the skin, tuberculosis, acne rosacea, perioral dermatitis, fungal skin infections and ulcerative conditions.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

If irritation or sensitisation develops with the use of NOVASONE Cream, Ointment or Lotion treatment should be discontinued and appropriate therapy instituted.

In the presence of an infection, 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 controlled adequately.

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

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated, if the occlusive technique is used, if used in areas where the epidermal barrier is disrupted or if used long-term. Suitable precautions should be taken to ensure application sites are not occluded, particularly in infants and children (see **Section 4.4 Special Warnings and Precautions for Use, Paediatric use**).

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.

NOVASONE Cream, Ointment and Lotion are not for ophthalmic use.

Use in the elderly

No data available.

Paediatric use

In infants, plastic pants and napkins may act as occlusive dressings and increase absorption. Paediatric patients may demonstrate greater susceptibility to topical corticosteroid induced HPA axis suppression and Cushing's syndrome than adults because of a larger skin surface area to body weight ratio. Use of topical corticosteroids in children should be limited to the least amount required for a therapeutic effect. Chronic corticosteroid therapy may interfere with growth and development of children.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No data available.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy (Category B3)

Category B3: Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have shown evidence of an increased occurrence of foetal damage, the significance of which is considered uncertain in humans.

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Similarly mometasone furoate has been shown to be teratogenic after dermal application to animals. At doses greater than 0.3 mg/kg in rats and at all dose levels tested in rabbits (0.15 mg/kg and 0.3 mg/kg), sequelae typical of other topical corticosteroids resulted. There are no adequate and well controlled studies of the teratogenic

effects of corticosteroids in pregnant women. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Drugs of this class should not be used on pregnant patients in large amounts or for prolonged periods of time.

Use in lactation

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether breast-feeding should be discontinued or NOVASONE Cream, Ointment or Lotion be discontinued, taking into account the importance of the drug to the mother.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

NOVASONE Cream, Ointment and Lotion are generally well tolerated. Pruritus, burning, tingling/stinging, signs of skin atrophy and acneiform reaction have been reported in less than 5% of patients.

Other local adverse reactions reported in less than 1% of patients include erythema, furunculosis, dermatitis, abscess, aggravated allergy, increased lesion size, disease exacerbation, paraesthesia, dry skin, pimples, folliculitis and papular and pustular formation.

The following local adverse reactions have been reported infrequently with the use of other topical corticosteroids: irritation, hypertrichosis, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

Systemic adverse reactions, such as vision blurred, have also been reported with the use of topical corticosteroids.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at <http://www.tga.gov.au/reporting-problems>.

4.9 OVERDOSE

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

Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Mometasone furoate is a synthetic corticosteroid, exhibiting anti-inflammatory, antipruritic and vasoconstrictive properties.

In laboratory animals, mometasone furoate exhibits potent topical anti-inflammatory activity but approximately half of the suppressive effect on the HPA (hypothalamic-pituitary-adrenal) axis when compared with equivalent doses of betamethasone valerate. The topical to systemic potency ratio of mometasone furoate is approximately 3 to 10 times that of betamethasone valerate in animal studies.

Clinical trials

A single-blind, randomised, single exposure study was conducted in 165 healthy subjects to assess the relative vasoconstrictive potency of the new reformulated NOVASONE cream containing hydrogenated phosphatidylcholine in comparison to an initially marketed formulation. The primary objective of this study was to assess the relative vasoconstrictive potency as determined by skin blanching as measured by a chromameter. Results from the study show the new formulated NOVASONE cream is bioequivalent to the initially marketed formulation.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Following topical application of radio-labelled mometasone furoate in animals, systemic absorption was minimal in all species studied, ranging from approximately 2% in dogs to 11% in rabbits over a 5 to 7 day period.

The percutaneous absorption of NOVASONE was evaluated in healthy volunteers receiving a single application of radio-labelled mometasone furoate cream 0.1% which remained on intact skin for eight hours. Based on the radioactivity excreted in the urine and faeces during the five day study period, approximately 0.4% of the applied dose was absorbed systemically. In a similar study conducted using the ointment formulation, approximately 0.7% of the applied dose was absorbed systemically.

Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. As NOVASONE is applied topically and only low concentrations of radioactivity are detected in plasma, specific bioavailability studies have not been conducted for mometasone furoate.

No pharmacokinetic studies were conducted with the new NOVASONE cream formulation.

Distribution

No data available.

Metabolism

Since plasma levels of radio-labelled product are very low, metabolism in humans has not been studied.

Excretion

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Each gram of NOVASONE Cream contains mometasone furoate 1 mg in a cream base of:

White soft paraffin
Hexylene glycol
Hydrogenated soy phosphatidylcholine
Aluminium starch octenylsuccinate
White beeswax
Purified water
Titanium dioxide
Phosphoric acid

Each gram of NOVASONE Ointment contains mometasone furoate 1 mg in an ointment base of:

White soft paraffin
Hexylene glycol
White beeswax
Purified water
Propylene glycol monostearate
Phosphoric acid

Each gram of NOVASONE Lotion contains mometasone furoate 1 mg in a lotion base of:

Isopropyl alcohol
Propylene glycol
Hyprolose
Monobasic sodium phosphate dihydrate
Phosphoric acid
Purified water

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

The expiry date can be found on the packaging. In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG).

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Cream, Ointment and Lotion: Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

NOVASONE Ointment: 5 g*(S3), 15 g(S3), 45 g* and 50 g* tubes

NOVASONE Cream: 15 g(S3), 45 g and 50 g* tubes

NOVASONE Lotion: 5 mL*(S3), 10 mL*(S3), 15 mL*(S3), 20 mL*, 30 mL, 50 mL* and 100 mL* bottles

* not currently available in Australia

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

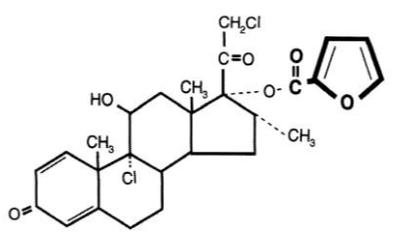
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Mometasone furoate is 9 α ,21-dichloro-11 β ,17-dihydroxy-16 α -methylpregna-1,4-diene-3,20-dione-17-(2-furoate). The empirical formula is C₂₇H₃₀Cl₂O₆. MW: 521.4.

Mometasone furoate is a white to off white powder practically insoluble in water, slightly soluble in octanol and moderately soluble in ethyl alcohol.

Chemical structure



CAS number

83919-23-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 4 – Prescription Only Medicines

Schedule 3 – Pharmacist Only Medicines (Pack Sizes 15 g or 15 mL or Less)

8 SPONSOR

Organon Pharma Pty Limited
Building A, 26 Talavera Road
Macquarie Park NSW 2113
Australia

9 DATE OF FIRST APPROVAL

NOVASONE Cream 11 September 2013

NOVASONE Ointment 19 February 1997

NOVASONE Lotion 19 February 1997

10 DATE OF REVISION

12 February 2021

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
Various sections	Editorial – correct spelling, Australian Approved Names
6.7	Add CAS number
7	Update to Medicine Schedule Section Schedule 3 for products 15 g or 15 mL or less
8	Update sponsor name and address details

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