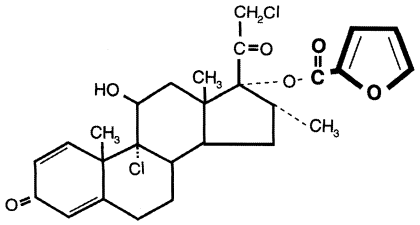
NOVASONE CREAM, OINTMENT AND LOTION
PRODUCT INFORMATION

NAME OF THE MEDICINE

Mometasone furoate 0.1% (1 mg/g)

Chemical structure:



Mometasone furoate is 9α,21-dichloro-11ß,17-dihydroxy-16α-methylpregna-1,4-diene-3,20-dione 17-(2-furoate). The empirical formula is $C_{27}H_{30}Cl_2O_6$. MW: 521.4.

DESCRIPTION

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

Each gram of NOVASONE Cream contains mometasone furoate 1mg in a cream base of soft white paraffin, hexylene glycol, soy phosphatidylcholine - hydrogenated, aluminium starch octenylsuccinate, white beeswax, purified water, titanium dioxide and phosphoric acid.

Each gram of NOVASONE Ointment contains mometasone furoate 1mg in an ointment base of soft white paraffin, hexylene glycol, white beeswax, purified water, propylene glycol monostearate and phosphoric acid.

Each gram of NOVASONE Lotion contains mometasone furoate 1mg in a lotion base of isopropyl alcohol, propylene glycol, hydroxypropylcellulose, sodium phosphate monobasic dihydrate, phosphoric acid and purified water.

PHARMACOLOGY

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.

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 soy phosphatidylcholine – hydrogenated 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.

Pharmacokinetics

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

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

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.

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.

PRECAUTIONS

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. 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.

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 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.

ADVERSE EFFECTS

NOVASONE Cream, Ointment and Lotion are generally well tolerated. Pruritis, 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.

DOSAGE AND 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.

OVERDOSAGE

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.

PRESENTATION AND STORAGE CONDITIONS

NOVASONE Ointment: 15 g, 50 g* tube.

NOVASONE Cream: 15 g, 50 g* tube

NOVASONE Lotion: 10 mL*, 15 mL*, 20 mL*, 30 mL, 50 mL* and 100 mL* bottles

* not currently available in Australia

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

NAME AND ADDRESS OF THE SPONSOR

Merck Sharp & Dohme (Australia) Pty Limited
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POISON SCHEDULE OF THE MEDICINE

Schedule 4 – Prescription Only Medicines

DATE OF APPROVAL

This product information was approved by the Therapeutic Goods Administration on 22 July 2013.

Date of most recent amendment: 30 January 2018