

# **MONTAZONE**

**Ointment**

## **Composition**

Mometasone furoate 1 mg/g (0.1% w/w)

## **Action**

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

## **Mechanism of Action**

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.

The local irritation and sensitization potentials of mometasone furoate cream and ointment were evaluated in rabbits and guinea pigs. Following topical application in rabbits, the dermal response to mometasone furoate cream was characterized by very slight erythema, occasional appearance of papules, atonia, desquamation and wrinkling. Mometasone furoate was not a sensitizer in guinea pigs.

## **Pharmacokinetics**

Following topical application of radio-labeled mometasone furoate in animals, systemic absorption was minimal in all species studied, ranging from approximately 2% in dogs to 6% in rabbits over a 5 to 7 day period.

The percutaneous absorption of mometasone furoate was evaluated in healthy volunteers receiving a single application of radio labeled 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.

## **Indications**

Montazone Ointment is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, such as psoriasis and atopic dermatitis.

## **Contraindications**

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

## **Adverse Reactions**

Mometasone is generally well tolerated. Pruritis, burning, tingling, stinging, and signs of skin atrophy, folliculitis 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 and papular and pustular formation.

## **Warnings and Precautions**

If irritation or sensitization develops with the use of mometasone, 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 favorable response does not occur promptly, mometasone should be discontinued until the infection is controlled adequately.

Babies and children up to four years should not be treated with topical steroids for longer than three weeks. In infants the napkin may act as an occlusive dressing and increase absorption. Adrenal suppression is more likely to occur in infants and children.

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 or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long term use is anticipated, particularly in infants and children. 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.

Mometasone should not be used on or around the eyes. The use of topical corticosteroids on the face can exacerbate rosacea and lead to peri-orofacial dermatitis. Patients should be warned against using mometasone on the face except on medical advice and any use on the face should be restricted to short periods.

Prolonged use on flexures and intertrigenous areas is undesirable.

### **Pregnancy**

#### *Category C*

Safe use of mometasone in pregnant women has not been established. Topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used on pregnant patients in large amounts or for prolonged periods of time.

### **Nursing Mothers**

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 breastfeeding should be discontinued or mometasone be discontinued, taking into account the importance of the drug to the mother.

Topical corticosteroids should not be applied to the breasts prior to nursing.

### **Dosage and Administration**

A thin film of Montazone Ointment should be applied to the affected skin areas once daily. Montazone Ointment should be used for dry, scaling and fissured lesions.

### **Overdosage**

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

### **Storage**

Store below 30°C. Medicines should be kept out of the reach of children.

### **Presentation**

Tube of 15 grams