PACKAGE INSERT

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

MOMATE 0,1 % CREAM

COMPOSITION:

Each gram of the cream contains 1 mg of mometasone furoate in a cream base.
Other ingredients of the product are aluminium starch octenylsuccinate, hexylene glycol, phosphoric acid, phospholipon 90 H, purified water, titanium dioxide, white petrolatum and white wax.

PHARMACOLOGICAL CLASSIFICATION:

A 13.4.1 Corticosteroids with or without anti-infective agents

PHARMACOLOGICAL ACTION:

Pharmacodynamics properties

Mometasone is a medium-potency synthetic topical steroid that has anti-inflammatory, antipruritic and vasoconstrictive actions.

Pharmacokinetics properties

A minimal amount of mometasone is absorbed after topical application to normal skin. That which is absorbed is metabolised in the liver and excreted in the urine.

INDICATIONS:

MOMATE 0,1 % CREAM is indicated for the relief of inflammatory manifestations of psoriasis and corticosteroid-responsive dermatoses.

CONTRAINDICATIONS:

MOMATE 0,1 % CREAM is contraindicated in those who are sensitive to any of the ingredients. MOMATE 0,1 % CREAM must not be used in the treatment of viral infections such as, herpes simplex, vaccine or varicella. It is also contra-indicated in patients with untreated fungal infections.
MOMATE 0,1 % CREAM is contraindicated in pregnancy and lactation (See “PREGNANCY AND LACTATION”).
Corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents may be absorbed percutaneously, teratogenicity following topical application

cannot be excluded. Therefore, MOMATE 0,1 % CREAM should not be used during pregnancy.

WARNINGS and SPECIAL PRECAUTIONS:

WARNINGS:

MOMATE 0,1 % CREAM is not for ophthalmic use. Safety and efficacy of MOMATE 0,1 % CREAM in paediatric patients for more than three weeks of use have not been established. Use in paediatric patients under the age of two years is not recommended.

Potent topical corticosteroid preparations, such as MOMATE 0.1 % CREAM, should not be applied to any skin crease areas.

MOMATE 0.1 % CREAM should especially not be applied in the nappy area of infants.

SPECIAL PRECAUTIONS:

Safety of use for more than three weeks has not been established and MOMATE 0.1 % CREAM should therefore be used for short courses only.

Use with caution near the eyes (See “WARNINGS”).

Discontinue treatment if irritation or sensitisation occurs and treat appropriately. In facial dermatoses, MOMATE 0,1 % CREAM should be used cautiously and for short periods only, as a steroid rosacea-like facies may be produced.

Systemic absorption may occur, especially when large quantities of the cream are used or applied to large areas of the body or to damaged skin and when an occlusive dressing technique is applied. This may result in benign intracranial hypertension.

If MOMATE 0,1 % CREAM is used for the treatment of psoriasis, pustular form of the disease may be provoked.

If a secondary bacterial infection is present, suitable concomitant antimicrobial therapy should be applied.

Effects on the Ability to Drive or Operate Machinery

MOMATE 0,1 % CREAM has no side effects such as dizziness or drowsiness, which may affect the ability to drive or operate machinery.

INTERACTIONS:

There are no studies on interactions with the topical use of MOMATE 0,1 % CREAM.

PREGNANCY AND LACTATION:

MOMATE 0,1 % CREAM should not be used in pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:

A thin film of MOMATE 0,1 % CREAM should be applied to completely cover the whole affected area once daily.

MOMATE 0,1 % CREAM may be used with caution in paediatric patients from the age of two years and older.

Treatment should be discontinued once the condition is under control. Duration of therapy is dependent on clinical response and may vary from a few days to a longer period of time. It should, however, not be continued for longer than three weeks without the patient being re-evaluated.

SIDE EFFECTS:

SIDE EFFECTS

Long-term continuous therapy with MOMATE 0,1 % CREAM may cause atrophic changes in the skin leading to thinning, loss of elasticity, dilatation of superficial blood vessels, telangiectasiae and ecchymoses, especially if applied to the face or if occlusive dressings are used.

Endocrine disorders:

Less frequent:

Cushingoid state, depression of the hypothalamic-pituitary-adrenal axis with consequent suppression of the adrenal gland, and growth retardation may occur. These effects are most likely to be severe in children.

Skin and subcutaneous tissue disorders:

Less frequent:

Allergic contact dermatitis, burning, dryness, folliculitis, irritation, itching, secondary infection, and skin atrophy, acneiform eruptions, perioral dermatitis, hypertrichosis, hypopigmentation, miliaria, maceration of the skin and striae.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Refer to **"SIDE EFFECTS and WARNINGS and SPECIAL PRECAUTIONS".**

Excessive or prolonged use of MOMATE 0,1 % CREAM can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency, but may also produce manifestations of hypercorticism, including Cushing's syndrome.

Acute hypercortism, including Cushing's syndrome.

Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of MOMATE 0,1 % CREAM is advised. Treatment is symptomatic and supportive.

IDENTIFICATION:

Smooth, white to off-white cream, free from grittiness.

PRESENTATION:

MOMATE 0,1 % CREAM is packaged in 20 g laminated closed end nozzle aluminium tube with milky white cap having a piercing point.

STORAGE INSTRUCTIONS:

Store at or below 25º C. Do not refrigerate.

Keep well closed and protect against light.

For external use only.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:

43/13.4.1/0250

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Activo Health (Pty) Ltd

Block B, Arena Office Park

272 West Avenue

Centurion

0157

DATE OF PUBLICATION OF THE PACKAGE INSERT

29 May 2023