PACKAGE INSERT

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

MOMATE OINTMENT

COMPOSITION:

Each gram of the ointment contains 1 mg of mometasone furoate in ointment base.

Other ingredients of the product are hexylene glycol, phosphoric acid, propylene-glycol (55 % monoester), purified water, white petroleum and white wax.

PHARMACOLOGICAL CLASSIFICATION:

A 13.4.1 Corticosteroids with or without anti-infective agents

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

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

Pharmacokinetic 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 OINTMENT is indicated for the relief of inflammatory manifestations of psoriasis and corticosteroid-responsive dermatoses.

CONTRAINDICATIONS:

MOMATE OINTMENT is contra-indicated in those who are sensitive to any of the ingredients. MOMATE OINTMENT is contra-indicated in treatment of viral infections such as, herpes simplex, vaccinia and varicella. It is also contra-indicated in patients with untreated fungal infections. MOMATE OINTMENT is contra-indicated in pregnancy and lactation (See "PREGNANCY AND LACTATION").

Corticosteriods 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 OINTMENT should not be used in pregnancy.

WARNINGS AND SPECIAL PRECAUTIONS:

WARNINGS:

MOMATE OINTMENT is not for ophthalmic use. Safety and efficacy of MOMATE OINTMENT 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.

Potential topical corticosteroid preparations, such as MOMATE OINTMENT, should not be applied to any skin crease areas.

MOMATE OINTMENT 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 OINTMENT should therefore be used for short courses only.

Use with caution near the eyes (See "WARNINGS").

If MOMATE OINTMENT 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.

INTERACTIONS:

There are no known interactions with the topical use of MOMATE OINTMENT.

PREGNANCY AND LACTATION:

MOMATE OINTMENT should not be used in pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:

A thin film of MOMATE OINTMENT should be applied to completely cover the whole affected area once daily.

MOMATE OINTMENT 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:

Long-term continuous therapy with MOMATE OINTMENT 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 **"WARNINGS AND SPECIAL PRECAUTIONS".**

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

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

IDENTIFICATION:

Translucent white soft ointment

PRESENTATION:

MOMATE OINTMENT is packaged in 20 g and 30 g closed end nozzle laminated collapsible aluminium tubes and 45 g close end nozzle laminated tubes.

STORAGE INSTRUCTIONS:

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

Keep well closed and protect against light.

For external use only.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:

44/13.4.1/0095

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:

To be allocated.