1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS S4

PROPRIETARY NAME AND DOSAGE FORM

PERSIVATE OINTMENT

PERSIVATE (cream)

COMPOSITION

Each 5 g of PERSIVATE OINTMENT contains betamethasone valerate equivalent to 5 mg betamethasone.

Each 5 g of PERSIVATE cream contains betamethasone valerate equivalent to 5 mg betamethasone.

Excipients:

PERSIVATE OINTMENT: Beeswax white, cholesterol, propylene glycol, stearyl alcohol, white soft paraffin.

PERSIVATE cream: Cetyl alcohol, chlorocresol, emulsifying wax, liquid paraffin, propylene glycol, purified water.

Preservative:

PERSIVATE cream: Chlorocresol 0,1 % *m/m*

CATEGORY AND CLASS

A 13.4.1 Corticosteroids with or without anti-infective agents

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Betamethasone valerate is a potent topical corticosteroid which exhibits anti-inflammatory and anti-allergic properties when applied to the skin and mucosa.

The mechanism of action is related to causing vasoconstriction, stabilizing lysosomal membranes, suppressing cell division and suppressing the immune response.

INDICATIONS

Non-infected steroid responsive dermatoses.

CONTRAINDICATIONS

PERSIVATE is contraindicated in the treatment of herpes simplex, vaccinia or varicella.

Long term use is contraindicated in patients with diabetes mellitus or tuberculosis.

WARNINGS AND SPECIAL PRECAUTIONS

FOR EXTERNAL USE ONLY.

KEEP OUT OF REACH OF CHILDREN.

Systemic absorption of topically applied PERSIVATE may occur, particularly under the following conditions; when large quantities are used, or when application is made to wide areas of the body or to damaged skin, and when the occlusive dressing technique is applied. Depression of the hypothalmic-pituitary-adrenal axis with consequent suppression of the adrenal gland may occur, and may be precipitated by an infection or trauma. These effects are most likely to be severe in children.

The use of PERSIVATE during pregnancy is not recommended.

Treatment should be discontinued if unfavourable reactions are seen. Regular review should be made of the necessity for continuing therapy.

If a secondary microbial skin infection is present suitable concomitant antimicrobial therapy should be instituted.

PERSIVATE should not be used to treat infections and ulcers of the leg. It causes delayed wound healing and increased liability to infections.
PERSIVATE should not be applied to any skin crease areas.

PERSIVATE should be used with caution near the eyes and should be used for short courses only. Application to the eyes has produced corneal ulcers, raised intraocular pressure, and reduced visual function.

The treatment of psoriasis with PERSIVATE may provoke the pustular form of the disease.
PERSIVATE should not be used on infants and young children.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

The use of PERSIVATE during pregnancy is not recommended.

DOSAGE AND DIRECTIONS FOR USE

PERSIVATE OINTMENT: Apply to the affected areas 2 or 3 times daily by gentle inunction or use with occlusive dressings.

PERSIVATE cream: Apply to the affected areas 2 to 3 times daily by gently inunction.

SIDE EFFECTS

Local effects include atrophy of the epidermis and dermal collagen (causing atrophic striae), drying and thinning of the skin, loss of elasticity, dilatation of superficial blood vessels, telangiectasiae and ecchymoses. Increased fragility of cutaneous vessels may result in bruising and purpura. Rosacea-like dermatitis, perioral dermatitis, hypopigmentation and acneiform eruptions occur. These changes are particularly likely to occur on the face and when occlusive dressings are used. Occlusive dressings are associated with maceration of the skin and miliaria. Local infection may be worsened and spread enhanced.

Growth retardation in children has been reported and a Cushingoid state may be produced. Benign intracranial hypertension has been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

See SIDE EFFECTS.

Treatment

Treatment is supportive and symptomatic.

IDENTIFICATION

PERSIVATE OINTMENT: A soft, smooth, translucent whitish ointment.

PERSIVATE cream: A soft, smooth, white cream.

PRESENTATION

PERSIVATE OINTMENT:

15 g is packed in an aluminium collapsible tube, sealed with a white, self-piercing, high density polyethylene screw-cap, and placed in a unit cardboard carton together with a leaflet.

500 g is packed into a white round high density polyethylene jar sealed with a white, polypropylene screw-cap.

PERSIVATE cream:

15 g is packed in an aluminium collapsible tube, sealed with a white, self-piercing, high density polyethylene screw-cap, and placed in a unit cardboard carton together with a leaflet.

500 g is packed into a white round high density polyethylene jar sealed with a white, polypropylene screw-cap.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS

PERSIVATE OINTMENT: L/13.4.1/395

PERSIVATE cream: L/13.4.1/382

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration:

PERSIVATE OINTMENT: 06 June 1980

PERSIVATE cream: 15 June 1981

Date of the most recent amendment to the professional information as approved by the Authority: 15 June 1981

Botswana:	S2
PERSIVATE OINTMENT:	BOT0901496
PERSIVATE cream:	B9322635

Namibia:	NS2
PERSIVATE OINTMENT:	90/13.4.1/001108
PERSIVATE cream:	90/13.4.1/001109

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