PROPOSED PROFESSIONAL INFORMATION (clean)

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME AND DOSAGE FORM

Vari-Betamethasone Cream

COMPOSITION

Active ingredient:

Each 100 g contains betamethasone valerate equivalent to 0,1 g betamethasone.

Contains: chlorocresol 0,1 % *m/m* as preservative.

Inactive ingredients:

Cetomacrogol, cetostearyl alcohol, liquid paraffin, purified water and white soft paraffin.

PHARMACOLOGICAL CLASSIFICATION

A 13.4.1 Dermatological preparations – corticosteroids with or without anti-infective agents.

PHARMACOLOGICAL ACTION

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

Betamethasone valerate is classified as potency II (potent).

INDICATIONS

Non-infected steroid responsive dermatoses.

CONTRAINDICATIONS

Hypersensitivity to the preparation.

Rosacea, acne vulgaris, peri-oral dermatitis, peri-anal and genital pruritus, tuberculosis of the skin and varicose ulcers.

Skin lesions caused by infection with viruses (e.g. herpes simplex, vaccinia or varicella), fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo).

Vari-Betamethasone Cream should not be used in the nappy areas of infants for flexural eruptions or dermatoses in children under one year of age, including dermatitis.

Refer also to **HUMAN REPRODUCTION**.

WARNINGS AND SPECIAL PRECAUTIONS

For external use only.

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

In infants the nappy may act as an occlusive dressing, and hence these preparations should not be used in the nappy area for flexural eruptions. Ideally they should not be used in infants and young children at all.

Treatment of psoriasis with **Vari-Betamethasone Cream** (or its withdrawal) may provoke the pustular form of the disease.

Vari-Betamethasone Cream should be used with particular caution in facial dermatoses, and only for short periods. A steroid rosacea-like facies may be produced.

Vari-Betamethasone Cream should be used with caution near the eyes. Topical application of corticosteroid preparation to the eyes has produced corneal ulcers, raised intra-ocular pressure and reduced visual function.

Vari-Betamethasone Cream should not be used in skin crease areas.

Vari-Betamethasone Cream should not be used indiscriminately for pruritus.

Vari-Betamethasone Cream should never be used in the presence of infection except in conjunction with effective chemotherapy. Any spread of infection requires withdrawal of **Vari-Betamethasone Cream** therapy.

HUMAN REPRODUCTION

Corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore, **Vari-Betamethasone Cream** should not be used during pregnancy.

DOSAGE AND DIRECTIONS FOR USE:

A small quantity should be applied to the affected area two to three times daily until improvement occurs. It may then be possible to maintain improvement by applying once a day or even less often.

Vari-Betamethasone Cream is especially appropriate for moist or weeping surfaces.

Vari-Betamethasone Cream should be used for short courses only, as prolonged and intensive treatment may cause side effects.

SIDE EFFECTS

Endocrine disorders:

Prolonged use, use of large amounts, treatment of extensive areas, application to damaged skin, or when the occlusive dressing technique is applied, can result in sufficient systemic absorption to produce the features of hypercorticism such as depression of the hypothalamic-pituitary-adrenal axis with consequent suppression of the adrenal gland. These effects are most likely to be severe in infants and children. Growth may be retarded and a Cushingoid state may be produced.

Vascular disorders:

Benign intracranial hypertension has been reported.

Skin and subcutaneous tissue disorders:

Local atrophic changes in the skin such as striae, drying, thinning, loss of elasticity, dilatation of the superficial blood vessels, telangiectasia and ecchymoses. These changes are particularly likely to occur on the face, when occlusive dressings are used or where skin folds are involved. Pigmentation changes and hypertrichosis have been reported with the use of topical corticosteroids.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See **SIDE EFFECTS, AND WARNINGS AND SPECIAL PRECAUTIONS**. Treatment is symptomatic and supportive.

IDENTIFICATION

A white, smooth, homogeneous cream, free from any visible contaminants.

PRESENTATION

15 g and 50 g Aluminium lacquered tubes with a piercing cap.

500 g Brown HDPE jar with a white polypropylene cap.

STORAGE INSTRUCTIONS

Store at or below 25 °C, protected from light in a well-closed container. Do not refrigerate.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

34/13.4.1/0430

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

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