PACKAGE INSERT

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

Vari-Hydrocortisone 1 % Cream

COMPOSITION

Active ingredient:

Each gram contains 10 mg hydrocortisone.

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

Inactive ingredients:

Cetomacrogol, cetosterayl 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

Applied topically, hydrocortisone produces ant-inflammatory, anti-pruritic, anti-allergic and vasoconstrictive effects.

INDICATIONS

VARI-HYDROCORTISONE 1 % CREAM is indicated in the topical treatment of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

- Treatment of herpes simplex, vaccinia, varicella and tuberculosis of the skin.
- Patients with a history of sensitivity reactions to any of its components.
- Pregnancy and lactation.
- In the presence of acute infections uncontrolled by appropriate antimicrobial chemotherapy.

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.

WARNINGS AND SPECIAL PRECAUTIONS

VARI-HYDROCORTISONE 1 % CREAM is for external use only and not for ophthalmic use.

Topical administration of corticosteroids to patients with ocular herpes simplex infection can alleviate the symptoms but allow the infection to develop with the risk of irreversible corneal scarring that may lead to the loss of vision, or even loss of the eye.

Warnings have been sounded about the ocular risks of applying corticosteroids to the skin near the eyes. VARI-HYDROCORTISONE 1 % CREAM should be used with caution near the eyes.

VARI-HYDROCORTISONE 1 % CREAM should be used with particular caution in facial dermatoses, and only for short periods. A steroid rosacea-like facies may be produced.

INTERACTIONS

None known.

PREGNANCY AND LACTATION

The use of VARI-HYDROCORTISONE 1 % CREAM is contraindicated during pregnancy and lactation (see **CONTRAINDICATIONS**).

DOSAGE AND DIRECTIONS FOR USE

VARI-HYDROCORTISONE 1 % CREAM should be applied as a thin film to completely cover the affected area. The cream should be massaged gently and thoroughly into the skin. The usual frequency of application is twice daily.

Adequate maintenance therapy, when indicated, may be achieved with less frequent application in some patients.

SIDE EFFECTS

Infections and infestations:

Patients already receiving corticosteroid therapy are more susceptible to infection, the symptoms of which may be masked until an advanced stage has been reached.

If a secondary microbial infection is present, suitable concomitant antimicrobial therapy should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection has been controlled adequately.

Immune system disorders:

Should any irritation or sensitisation develop during the use of VARI-HYDROCORTISONE 1 % CREAM, treatment should be discontinued and appropriate therapy instituted.

Endocrine disorders:

Systemic absorption of VARI-HYDROCORTISONE 1 % CREAM may occur, particularly under the following conditions: when large quantities are used, when application is made to wide areas of the body, to damaged skin and when the occlusive dressing technique is applied. Depression of the hypothalamic-pituitary-adrenal axis with consequent suppression of the adrenal gland may occur.

These effects are most likely to be severe in children. Growth may be retarded and a Cushingoid state may be produced. Benign intracranial hypertension has been less frequently reported.

Skin and subcutaneous tissue disorders:

Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis.

Long-term continuous treatment with VARI-HYDROCORTISONE 1 % CREAM should be avoided as far as possible as this may cause atrophic changes in the skin leading to thinning, loss of elasticity, dilation of superficial blood vessels, telangiectasiae and ecchymoses. These changes are particularly likely to occur on the face and when occlusive dressings are used.

The following may occur more frequently with the use of occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT (See SIDE EFFECTS)

Symptoms

Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal

function, resulting in secondary adrenal insufficiency; but may also produce manifestations of hypercorticism, including Cushing's syndrome.

Treatment

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

IDENTIFICATION

VARI-HYDROCORTISONE 1 % CREAM is a homogenous, smooth, white cream free from any visible contaminants.

PRESENTATION

White aluminium lacquered tubes of 15 g or 20 g with piercing white plastic caps.

STORAGE INSTRUCTIONS

Keep container well closed. Store at or below 25 °C. Protect from light. Do not refrigerate.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

35/13.4.1/0384

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

Barrs Pharmaceutical Industries (Pty) Ltd

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DATE OF PUBLICATION OF THIS PACKAGE INSERT

Date of registration: 15 November 2002

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