APPROVED PACKAGE INSERT

SCHEDULING STATUS:

S2

PROPRIETARY NAME (AND DOSAGE FORM):

BIOCORT Cream

COMPOSITION:

Each 1 g contains:

Hydrocortisone Acetate	10 mg
Preservative:	
Chlorocresol	0,1% m/m

Excipients: chlorocresol, emulsifying wax, white soft paraffin, liquid paraffin and purified water.

PHARMACOLOGICAL CLASSIFICATION:

A. 13.4.1 Dermatological preparations: Corticosteroids with or without anti-infective agents.

PHARMACOLOGICAL ACTION:

BIOCORT cream has anti-inflammatory, antipruritic and vasoconstrictive properties.

INDICATIONS:

For the relief of corticosteroid-responsive dermatoses.

CONTRA-INDICATIONS:

Sensitivity to any of the ingredients.

Treatment of local viral infection such as herpes simplex, vaccinia or varicella (an acute exacerbation or systemic dissemination of these infections may be precipitated).

Should not be used in nappy areas in infants for flexural eruptions and ideally should not be used in infants or young children at all.

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 BIOCORT cream should not be used during pregnancy.

Do not apply to ulcers of the leg.

Do not use in treatment of rosacca.

WARNINGS AND SPECIAL PRECAUTIONS

FOR EXTERNAL USE ONLY.

Topical applications of corticosteroids should not be made with an occlusive dressing, to large areas of the body or where the skin is broken because of the increased risk of systemic toxicity.

Topical corticosteroids should in general not be used in the presence of infection.

However, occasionally they may be used with the addition of a suitable antimicrobial substance in the treatment of infected skin, but there is a risk of sensitivity reactions occurring.

Patients undergoing stress such as major surgery or severe infection, septicaemia, trauma, e.g. a motor vehicle accident, should receive replacement therapy to prevent a possible

adrenal crisis. The real incidence of such a crisis after the use of BIOCORT cream is not known; it is presumably uncommon.

BIOCORT cream should be used with particular caution in facial dermatoses. Special caution should be exercised in using BIOCORT cream near the eyes.
BIOCORT cream should be used for short treatment courses only. Long term topical use is best avoided, especially in children.

PREGNANCY AND LACTATION:

Use in pregnancy and lactation: See “Contraindications”

DOSAGE AND DIRECTIONS FOR USE:

After thorough cleaning of the affected area, a thin layer of cream is applied and rubbed gently into the affected area.

SIDE EFFECTS:

The continuous use of BIOCORT cream may result in atrophic changes in the skin leading to thinning, loss of elasticity, striae, dilation of superficial blood vessels, telangiectasiae and ecchymoses.

These changes are particularly likely to occur in areas of the greatest permeability such as the face, eyelids, axillae and scrotum and possibly the groin.
Mild depigmentation may also occur.
Acne spots may occur at the site of application.
Allergic contact dermatitis may be produced.
Systemic absorption is likely to occur when application is made to large areas of the body, or to damaged skin and when the occlusive dressing technique is applied.

Tight-fitting nappies to plastic pants should not be used on an infant being treated in the nappy area, as these garments may constitute as occlusive dressings.

Depression of the hypothalamic-pituitary-adrenal (HPA)-axis, with consequent suppression of the adrenal gland may occur.

Children may absorb proportionally large amounts of topical corticosteroids and thus be more susceptible to systematic toxicity.

Depression of the HPA-axis in children may retard growth and development in children.

Benign intracranial hypertension has been reported.

Cushing's syndrome may develop as results of continued and excessive absorption of BIOCORT cream, but this complication is very infrequent.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See "Side-effects".

Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION:

White to off-white cream.

PRESENTATION:

20 g and 25 g tubes and 500 g jars.

STORAGE INSTRUCTIONS:

Store at or below 25° C, protected from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

G2022 (Act 101/ 1965)

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

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