SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

QUADRIDERM®Cream

COMPOSITION

Each gram contains:

Betamethasone (as 17-valerate)	0.5 mg
Gentamicin (as sulphate)	1.0 mg
Tolnaftate	10.0 mg
Clioquinol	10.0 mg

Preservative: Chlorocresol 0.1% m/m

PHARMACOLOGICAL CLASSIFICATION

A.13.4.1 Corticosteroids with or without anti-infective agents

PHARMACOLOGICAL ACTION

QUADRIDERM®Cream is a highly effective topical dermatological preparation that provides a complete range of therapy in treating a large number of dermatological conditions. QUADRIDERM®Cream ensures a greater certainty of therapeutic success, especially when the causative agent is not readily identifiable.

QUADRIDERM®Cream combines an extremely active anti-inflammatory agent (betamethasone 17-valerate), a highly effective broad-spectrum antibiotic (gentamicin sulphate), a non-sensitising topical fungicidal agent effective against most tinea infections (tolnaftate) and a useful agent for the treatment of mixed dermatological infections caused by fungi including *Candida albicans* and gram-positive bacteria (clioquinol).

INDICATIONS

QUADRIDERM®Cream is indicated for topical use in the treatment of a wide variety of eczemas and other allergic and inflammatory steroid-responsive dermatoses. including pruritus, where secondary bacterial and/or fungal infection is present or threatens.

CONTRA-INDICATIONS

This preparation is contra-indicated in the treatment of tuberculosis and most viral lesions of the skin. particularly herpes simplex, vaccinia or varicella.

QUADRIDERM®Cream is contra-indicated in those patients demonstrating sensitivity to any of the ingredients. 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 QUADRIDERM®Cream should not be used during pregnancy.

DOSAGE AND DIRECTIONS FOR USE

A sufficient quantity should be applied to completely cover the affected area two or three times a day or as prescribed by the doctor. Duration of therapy should be determined by patient response. In cases of tinea pedis, longer therapy (2 to 4 weeks) maybe necessary.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

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

Systemic absorption of topically applied corticosteroids 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 rarely reported.

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

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

Topical corticosteroid preparations should be used with caution near the eyes.

Potent topical corticosteroids should be used for short courses only. Regular review should be made of the necessity for continuing therapy.

These corticosteroid preparations should not be used in the nappy areas in infants for flexural eruptions, and ideally they should not be applied to infants and young children at all.

The treatment of psoriasis with potent topical corticosteroids may provoke the pustular form of the disease.

Slight staining of clothing might occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See "**SIDE EFFECTS AND SPECIAL PRECAUTIONS**".

Treatment is symptomatic and supportive.

IDENTIFICATION

An off-white cream.

PRESENTATION

Tubes of 15 g.

STORAGE INSTRUCTIONS

Store below 30°C.

Keep out of reach of children.

REFERENCE NUMBER

G2331 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT

Phyto OTC Health (Pty) Ltd

49 New Road

Midrand

South Africa

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