1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

MYLOCORT CREAM 1,0 g/ 100 g

MYLOCORT OINTMENT 1,0 g/ 100 g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g of MYLOCORT CREAM contains 1,0 g hydrocortisone acetate.

Preservative:

Chlorocresol 0,1 % *m/m*

Each 100 g of MYLOCORT OINTMENT contains 1,0 g hydrocortisone acetate.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

MYLOCORT CREAM is a smooth, white to off white cream.

MYLOCORT OINTMENT is a smooth, off-white Vaseline-like ointment.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the temporary relief of itching associated with minor skin irritations due to eczema, insect bites, poison plants, soaps, detergents, cosmetics, jewellery, seborrhoeic dermatitis and for the relief of external genital and anal itching. Other uses for the medicine should be only under the advice and supervision of a doctor.

4.2. Posology and method of administration

Posology

MYLOCORT should be applied to the affected area up to four times a day until improvement occurs, when the frequency of application may be reduced.

Do not use MYLOCORT for longer than 7 days (see section 4.4).

Do not put MYLOCORT into the rectum by using fingers or any mechanical device or applicator.

MYLOCORT CREAM is usually suitable for moist or weeping surfaces, whereas MYLOCORT OINTMENT should be considered for dry, scaly or lichenified conditions.

Paediatric population

Do not use in children under the age of two (see section 4.3).

Do not use in children under the age of 12 years for indications pertaining to genital and anal use (see section 4.3).

Method of administration

For topical administration.

After thorough cleaning of the affected skin, a thin layer of MYLOCORT is applied by smoothing gently into the affected area/s. No additional benefit is gained by vigorous rubbing.

4.3. Contraindications

MYLOCORT is contraindicated in:

- Patients with hypersensitivity to hydrocortisone or to any of the excipients in MYLOCORT (see section 6.1).
- The presence of vaginal discharge.
- Cosmetic purposes.
- External anal itching accompanied by bleeding.
- Nappy rash (see section 4.4).
- Children under the age of 12 years for indications pertaining to genital and anal use (see section 4.2).
- Children under the age of 2 years (see section 4.2).
- Untreated bacterial (e.g. impetigo), viral (e.g. herpes simplex, vaccinia or varicella), or fungal (e.g. candida or dermatophyte) infections.
- Tuberculosis of the skin and varicose ulcers.
- Scabetic infections.
- Rosacea.
- Perioral dermatitis.
- Pregnancy and lactation (see section 4.6).
- Use on the eyes or on broken skin.
- Acne.

4.4. Special warnings and precautions for use

For external use only. Avoid contact with the eyes (see section 4.2).

Facial dermatoses and atrophic skin changes

MYLOCORT should be used with particular caution in facial dermatoses and only for short periods as a steroid rosacea-like facies may be produced. Topical treatment with MYLOCORT for longer than 7 days should be avoided as this may cause atrophic changes in the skin leading to thinning, loss of elasticity, dilation of superficial blood vessels, telangiectasiae and ecchymosis and local hypopigmentation of deeply pigmented skins. These changes are particularly likely to occur on the face and when occlusive dressings are used.

Systemic absorption

Systemic absorption can result in suppression of the hypothalamic pituitary adrenal axis with consequent suppression of the adrenal gland. Systemic absorption of topically applied MYLOCORT particularly occurs when large quantities are used, when application is made to wide areas of the body or to damaged skin, when the occlusive dressing technique is applied or when applied to skin folds and moist areas and when applied to the nappy areas in young children (see section 4.3). 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 reported.

If the treatment continues longer than two weeks, the risk of systemic side effects will increase especially in children. In infants and children, long-term continuous topical therapy should be avoided, as adrenal suppression can occur, even without occlusion. MYLOCORT should not be used for longer than 7 days. The use of MYLOCORT in dermatoses of infancy, including nappy rash, is contraindicated. In infants the nappy may act as an occlusive dressing and increase absorption.

Secondary microbial skin infections

If a secondary microbial skin infection is present, suitable concomitant antimicrobial therapy should be instituted. Any spread of infection requires withdrawal of MYLOCORT and systemic administration of antimicrobial medicines (see *Topical steroid withdrawal syndrome* below).

Psoriasis

Topical corticosteroids such as MYLOCORT should be used with caution in psoriasis. As rebound relapses, development of tolerances, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin have been reported in some cases. If used in psoriasis careful patient supervision is important.

Topical steroid withdrawal syndrome

Long term continuous or inappropriate use of topical steroids, as contained in MYLOCORT, can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

Visual impairment

Visual impairment may be reported with systemic and topical use of corticosteroids, as contained in MYLOCORT. If patients develop symptoms such as blurred vision or other

visual disturbances, consideration should be given to referring the patient to an ophthalmologist to establish the possible cause which may include cataract, glaucoma or rare conditions such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids (see section 4.8).

Excipients

MYLOCORT CREAM contains chlorocresol amongst the excipients which may cause allergic reactions. Treatment with MYLOCORT CREAM should be discontinued if this occurs (see section 6.1).

4.5. Interaction with other medicines and other forms of interaction

No interactions have been reported for MYLOCORT.

4.6. Fertility, pregnancy and lactation

Fertility

No fertility data are available.

Pregnancy

Corticosteroids such as MYLOCORT have been shown to be teratogenic in animals following dermal application. As these medicines are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore, MYLOCORT should not be used during pregnancy (see section 4.3).

Lactation

There is no information about effects during lactation. The use of MYLOCORT during lactation is not recommended (see section 4.3).

4.7. Effects on ability to drive and use machines

Since adverse reactions such as blurred vision have been reported in patients using MYLOCORT, patients should not drive, use machinery or perform any tasks that require concentration until they are certain that MYLOCORT does not adversely affect their ability to do so safely (see section 4.4 and 4.8).

4.8. Undesirable effects

a) Tabulated list of adverse reactions

System organ class	**Frequent**	**Less frequent**	**Frequency unknown** (cannot be estimated from available data)
Immune system disorders		Allergic reactions, hypersensitivity reactions	
Endocrine disorders		Suppression of the hypothalamic pituitary adrenal axis (see section 4.4)	
Nervous system disorders		Benign intracranial hypertension	
Eye disorders			Blurred vision (see section 4.4)
Skin and subcutaneous tissue disorders		Loss of skin collagen, atrophic changes in the skin leading to thinning, loss of elasticity, dilation of superficial blood vessels, telangiectasiae and ecchymoses, hypopigmentation of deeply	Withdrawal reactions- redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules (see section 4.4)

		pigmented skin (see section 4.4)	

b) Description of selected adverse reactions

Hydrocortisone, as contained in MYLOCORT, is usually well tolerated but if hypersensitivity occurs discontinue use.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to **SAHPRA** via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

4.9. Overdose

Symptoms

Acute over dosage is very unlikely to occur, however, in the case of chronic over dosage, use under occlusive dressings or misuse the features of hypercorticism may appear and in this situation topical steroids should be discontinued.

Treatment

There are no special procedures or antidote. Treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and class: A 13.4.1 Corticosteroid with or without anti-infective agent

Pharmacotherapeutic group: Corticosteroids, potent (group III)

ATC code: D07AA02

Mechanism of action

Hydrocortisone has anti-inflammatory, anti-pruritic, anti-allergic and vasoconstrictive effects.

Hydrocortisone is the main glucocorticoid secreted by the adrenal cortex. It is used topically for its anti-inflammatory effects, mediated by the reduction of formation, release and action of the various vasoactive chemicals released during inflammation.

5.2. Pharmacokinetic properties

Absorption

Hydrocortisone is absorbed systemically from sites of local administration such as the skin, particularly in denuded areas. When administration is prolonged, when the site of application is covered with an occlusive dressing, or when large areas of skin are involved, absorption may be sufficient to cause systemic effects, including suppression of the HPA axis (see section 4.4).

Distribution

Hydrocortisone is distributed to all body tissues. It crosses the placenta and may be excreted in small amounts in breast milk. Hydrocortisone in the circulation is usually extensively bound to plasma proteins, mainly to globulin and less so to albumin.

Biotransformation

Hydrocortisone is metabolised in the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol.

Elimination

The metabolites are excreted in the urine mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

MYLOCORT CREAM: Chlorocresol, emulsifying wax, purified wax, yellow soft paraffin.

MYLOCORT OINTMENT: Liquid paraffin, white soft paraffin.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

MYLOCORT CREAM: 24 months

MYLOCORT OINTMENT: 24 months

6.4. Special precautions for storage

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

6.5. Nature and contents of container

MYLOCORT CREAM: 25 g is filled into an epoxy-lined aluminium sealed tube, sealed with a high-density polyethylene screw-cap and placed in a unit cardboard carton together with a leaflet.

MYLOCORT OINTMENT: 25 g is filled into an epoxy-lined aluminium sealed tube, sealed with a high-density polyethylene screw-cap and placed in a unit cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed

6.6. Special precautions for disposal and other handling

No special precautions.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8. REGISTRATION NUMBERS

MYLOCORT CREAM: P/13.4.1/93

MYLOCORT OINTMENT: P/13.4.1/112

9. DATE OF FIRST AUTHORISATION

Date of registration:

MYLOCORT CREAM: 12 March 1982

MYLOCORT OINTMENT: 09 June 1982

10. DATE OF REVISION OF TEXT

31 December 2023

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.

Namibia: NS1

MYLOCORT CREAM: 90/13.4.1/001624

MYLOCORT OINTMENT: 90/13.4.1/001625

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