1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

LENOVATE CREAM

LENOVATE OINTMENT

COMPOSITION

Each 5 g of LENOVATE CREAM contains 5 mg of betamethasone as betamethasone valerate.

Excipients:

Chlorocresol, cetyl alcohol, citric acid monohydrate (for pH adjustment), disodium hydrogen phosphate (for pH adjustment), emulsifying wax, liquid paraffin, propylene glycol, purified water

Preservative:

Chlorocresol 0,1 % *m/m*

Each 5 g of LENOVATE OINTMENT contains 5 mg of betamethasone as betamethasone valerate.

Excipients:

Beeswax, cholesterol, propylene glycol, stearyl alcohol, white soft paraffin

PHARMACOLOGICAL CLASSIFICATION

A 13.4.1 Corticosteroids with or without anti-infective agents.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

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

The mechanism of action is related to causing vasoconstriction, stabilising lysosomal membranes, suppressing cell division and suppressing the immune response.

Pharmacokinetic properties

Absorption

Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.

Distribution

The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary because circulating levels are well below the level of detection.

Metabolism

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids and metabolised, primarily in the liver.

Elimination

Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

INDICATIONS

LENOVATE is used for the treatment of non-infected steroid responsive dermatoses.

CONTRAINDICATIONS

- Hypersensitivity to betamethasone or any of the excipients in the formulation (see COMPOSITION).
- 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).
- Nappy areas of infants for flexural eruptions or dermatoses in children under one year of age, including dermatitis.
- Pregnancy (see PREGNANCY AND LACTATION). 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, LENOVATE should not be used during pregnancy.
- Long term use in patients with diabetes mellitus or tuberculosis.

WARNINGS

FOR EXTERNAL USE ONLY.

Potent topical corticosteroid preparations, such as LENOVATE, should not be applied to any skin crease areas.

INTERACTIONS

Co-administered medicines that can inhibit CYP3A4 (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure.

The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

PREGNANCY AND LACTATION

LENOVATE is contraindicated during pregnancy (see CONTRAINDICATIONS).

Safety and efficacy during lactation have not been established.

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.

DOSAGE AND DIRECTIONS FOR USE

LENOVATE OINTMENT: Apply a small quantity gently to the affected areas 2 or 3 times daily or use with occlusive dressings.

The effect may be enhanced by application of occlusive dressings.

LENOVATE CREAM: Apply gently to the affected areas 2 to 3 times daily.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Side effects

Immune system disorders

Less frequent: Hypersensitivity reactions

Endocrine disorders

Less frequent: Cushingoid features

Nervous system disorders

Less frequent: Benign intracranial hypertension

Skin and subcutaneous tissue disorders

Frequent: Local skin burning, pruritus

Less frequent: Atrophy of the epidermis and dermal collagen, atrophic striae, drying and thinning of the skin, loss of elasticity, dilatation of superficial blood vessels, telangiectasiae, ecchymoses, purpura, bruising, rosacea-like dermatitis, perioral dermatitis, hyperpigmentation, acneiform eruptions.

These changes are particularly likely to occur on the face and when occlusive dressings are used. Occlusive dressings are associated with maceration of the skin and miliaria.

Pigmentation changes, hypertrichosis, allergic contact dermatitis, exacerbation of symptoms, pustular psoriasis.

Local infection may be worsened and spread enhanced.

Musculoskeletal, connective tissue and bone disorders

Less frequent: Growth retardation in children

Special precautions

Systemic absorption of topically applied LENOVATE may occur, particularly under the following conditions; when large quantities are used, or when application is made to wide areas of the body or 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, and may be precipitated by an infection or trauma. These effects are most likely to be severe in children.

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

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

LENOVATE should not be used to treat infections and ulcers of the leg. It causes delayed wound healing and increased liability to infections.

LENOVATE should be used with caution near the eyes and should be used for short courses only. Application to the eyes has produced corneal ulcers, raised intraocular pressure, and reduced visual function.

The treatment of psoriasis with LENOVATE may provoke the pustular form of the disease.

LENOVATE should not be used on infants and young children.

Effects on ability to drive and use machines

Patients should be advised to exercise caution when driving a vehicle, operating machinery or performing tasks requiring alertness, if they experience any side effects that affects their ability to perform these tasks safely.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms

LENOVATE may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur.

Treatment

In the event of overdose, LENOVATE should be withdrawn gradually by reducing the frequency of application, or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.

Treatment is supportive and symptomatic.

IDENTIFICATION

LENOVATE CREAM: A soft, smooth, homogenous, white cream.

LENOVATE OINTMENT: A soft, smooth, translucent whitish ointment.

PRESENTATION

LENOVATE CREAM and LENOVATE OINTMENT:

15 g is packed in a collapsible, epoxy phenolic lined, aluminium metal tube sealed with a white high-density polyethylene screw-cap and placed in a unit cardboard carton.

500 g is packed in a white round high-density polyethylene jar sealed with a white polypropylene screw-cap.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Store in well closed containers.

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

LENOVATE CREAM: 27/13.4.1/0493

LENOVATE OINTMENT: 27/13.4.1/0308

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

PHARMACARE LIMITED

Building 12

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PACKAGE INSERT

Dates of registration:

LENOVATE CREAM: 01 June 1993

LENOVATE OINTMENT: 08 February 1996

Date of the most recently revised approved package insert: 12 December 2019

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

Botswana:	S2
LENOVATE CREAM:	BOT0600834
LENOVATE OINTMENT:	BOT0600833

Namibia:	NS2
LENOVATE CREAM:	04/13.4.1/0115
LENOVATE OINTMENT:	04/13.4.1/0116

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