PROFESSIONAL INFORMATION FOR

REPIVATE

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

REPIVATE 15 mg/15 g, cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15,0 g of cream contains betamethasone valerate equivalent to 15,0 mg betamethasone.

Each 500,0 g of cream contains betamethasone valerate equivalent to 500,0 mg betamethasone.

Preservatives: Methyl paraben 0,12 % *m/m*

Propyl paraben 0,04 % *m/m*

For the full list of excipients, see section **6.1**.

3. PHARMACEUTICAL FORM

Cream.

A white cream with no visible foreign particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

REPIVATE is indicated in non-infected steroid responsive dermatoses.

4.2 Posology and method of administration

Apply in a small quantity to the affected area 2 or 3 times daily.

REPIVATE should be used for short courses only.

4.3 Contraindications

REPIVATE is contraindicated in:

- Patients with hypersensitivity to betamethasone or to any of the excipients in REPIVATE (see section **6.1)**.
- In the treatment of herpes simplex, vaccinia or varicella and tuberculosis of the skin.
- Pregnancy, since corticosteroids have been shown to be teratogenic in animals following dermal application (see section **4.6**).
- Infants and young children.
- The treatment of infections and leg ulcers as it causes delayed wound healing and increased liability to infections.
- Untreated cutaneous infections:
    - rosacea,
    - acne vulgaris,
    - pruritis without inflammation,
    - perianal and genital pruritis,
    - perioral dermatitis.

4.4 Special warnings and precautions for use

- If unfavourable reactions occur, treatment should be discontinued.
- If secondary microbial skin infection is present, suitable concomitant anti-microbial therapy should be instituted.

- REPIVATE should be used with caution in facial dermatoses, and only for short periods.
- REPIVATE should be used with caution near the eyes. Application to the eyelids has caused raised intraocular pressure, corneal ulcers, and reduced visual function.
- The treatment of psoriasis with REPIVATE may provoke the pustular form of the disease.
- Regular review should be made of the necessity for continuing therapy.
- REPIVATE should not be applied to any skin crease areas.
- Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above are observed, withdraw the drug gradually by reducing the frequency of application, or by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency (see section **4.8**).
- Long term continuous or inappropriate use of topical steroids 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 advice is recommended in these cases or other treatment options should be considered.
- Risk factors for increased systemic effects are:
    - Potency and formulation of topical steroid.
    - Duration of exposure.
    - Application to a large surface area.

- Use on occluded areas of skin e.g., on intertriginous areas or under occlusive dressings (in infants the nappy may act as an occlusive dressing).
- Increasing hydration of the stratum corneum.
- Use on thin skin areas such as the face.
- Use on broken skin or other conditions where the skin barrier may be impaired.

Paediatric population

In comparison with adults, children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. This is because children have an immature skin barrier and a greater surface area to body weight ratio compared with adults.

- In infants and children under 12 years of age, treatment courses should be limited to five days and occlusion should not be used; long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression can occur.

Methyl paraben and propyl paraben

REPIVATE cream contains methyl paraben and propyl paraben which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed with REPIVATE.

4.6 Fertility, pregnancy, and lactation

Pregnancy

Studies in animals have shown that corticosteroids are absorbed percutaneously. Since, teratogenicity following topical application cannot be excluded, REPIVATE should not be used during pregnancy (see section **4.3**)

Fertility

There are no data in humans to evaluate the effect of topical corticosteroids on fertility.

4.7 Effects on ability to drive and use machines.

No or negligible influence on driving performance or the ability to operate machinery is anticipated based on the side effect profile of REPIVATE cream.

4.8 Undesirable effects

Tabulated list of adverse reactions

The following adverse reactions have been classified according to the following categories, frequent, less frequent and frequency unknown.

MedDRA system organ class	**Frequency**	**Side effects**
Infection and infestations	*Less frequent*	Opportunistic infection.
Immune system disorders	*Less frequent*	Hypersensitivity, generalized rash.

MedDRA system organ class	Frequency	Side effects
Endocrine disorders	*Less frequent*	Depression of the hypothalamic-pituitary-adrenal (HPA) axis with consequent suppression of the adrenal gland may occur resulting in growth retardation, a Cushingoid state, osteoporosis, glaucoma, hyperglycaemia/ glucosuria, cataract, hypertension, weight gain, decreased endogenous cortisol levels, alopecia or trichorrhexis. These effects are most likely to be severe in children or may be precipitated by an infection or trauma.
Skin and subcutaneous tissue disorders	*Frequent*	Pruritis, local skin burning/skin pain.
	Less frequent	Allergic contact dermatitis, dermatitis, erythema, rash, urticaria, pustular psoriasis, hypertrichosis, exacerbation of underlying symptoms, skin atrophy/thinning, loss of elasticity, dilatation of superficial blood vessels, telangiectasia, ecchymoses, skin dryness, skin wrinkling, striae, pigmentation changes - These effects are more common with long term continuous use and are secondary to HPA axis suppression. Increased fragility of cutaneous vessels may result in bruising and purpura. These changes are particularly likely to occur on the face and when occlusive dressings are used.

MedDRA system organ class	Frequency	Side effects
	Frequency not known	Withdrawal reactions presenting as redness of the skin which may extend beyond the initial affected area, burning or stinging, itching, skin peeling, oozing pustules (see section **4.4)**
Nervous system disorders	*Frequency unknown*	Benign intracranial hypertension has been reported.

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. Health care 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 or to Cipla Medpro (Pty) Ltd., by email: drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

See sections **4.4** and **4.8**.

Treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification

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

Pharmacotherapeutic group: Corticosteroids, potent (group III)

ATC code: D07AC01

Mechanism of action

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

Pharmacodynamic effects

REPIVATE is a topical corticosteroid which exhibits anti-inflammatory and anti-allergic properties when applied to the skin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol

Citric acid monohydrate

Disodium hydrogen ortho Phosphate anhydrous

Liquid paraffin

Methyl paraben

Propyl paraben

Propylene glycol

Purified water

Sodium lauryl sulphate

Sorbitan mono oleate

Yellow soft paraffin

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

For external use only.

6.5 Nature and contents of container

REPIVATE is packed in a 20 g aluminium tube or 500 g plastic jar.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

8. REGISTRATION NUMBER(s)

31/13.4.1/0688

Namibia: NS2 11/13.4.1/0123

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation: 31 July 2005

Latest renewal: Not applicable.

10. DATE OF REVISION OF THE TEXT

26 February 2024