



ELYS CHEMICAL INDUSTRIES LIMITED.

ELYVATE CREAM

(Betamethasone 0.1% w/w as Betamethasone Valerate)

Summary of Product Characteristics

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Name: Elyvate Cream

1.1 Strength

Betamethasone 0.1% w/w as Betamethasone Valerate

1.2 Pharmaceutical form

Topical cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone Valerate equivalent to Betamethasone 0.1% W/W

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream

A white, smooth, homogenous cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Elyvate cream is indicated for topical treatment of corticosteroid responsive dermatoses such as atopic eczema, contact dermatitis, anogenital pruritis, seborrheic dermatitis, neurodermatitis and psoriasis. The cream is water-miscible and suitable for application on moist lesions and to the face.

4.2 Posology and method of administration

The cream should be applied sparingly to the affected areas twice daily for 3 to 6 weeks. Recurrence is common if the full course of treatment is not completed.

Method of administration

For cutaneous use



ELYS CHEMICAL INDUSTRIES LIMITED.

ELYVATE CREAM

(Betamethasone 0.1% w/w as Betamethasone Valerate)

Summary of Product Characteristics

4.3 Contraindications

Hypersensitivity to Betamethasone, infections of the skin including leg ulcers, herpes simplex, rosacea and acne vulgaris.

4.4 Special warnings and precautions for use

Topical application of corticosteroids should not be made with an occlusive dressing to large areas of the body due to the increased risk of systemic toxicity. The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment. Care should therefore be taken when treating conditions like psoriasis, discoid lupus erythromatosus and severe eczema. If applied to the eyelids, care should be taken to avoid entry into the eyes. long term topical use should be avoided especially in children and pregnant women. if hypersensitivity reactions or superinfection starts to occur, use should be discontinued.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There is a limited amount of data from the use of betamethasone in pregnant women. Betamethasone can be used during pregnancy but only under the supervision of a physician or midwife. Available pharmacodynamic/toxicological data in animals have shown excretion of betamethasone/metabolites in milk after intravenous administration.

Topical application is not expected to result in significant maternal absorption, and should not be of significant risk to a breast-feeding infant.

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Betamethasone therapy considering the benefit of breast-feeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines

Betametasone cream has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

Elyvate, when sparingly applied to the skin and used for short periods of time is devoid of systemic side effects as it is not significantly absorbed. Topical application may however lead to loss of skin collagen and hypopigmentation, sensitivity reactions and opportunistic infection with organisms such as fungi



ELYS CHEMICAL INDUSTRIES LIMITED.

ELYVATE CREAM

(Betamethasone 0.1% w/w as Betamethasone Valerate)

Summary of Product Characteristics

may also occur. The risk of side effects including systemic toxicity is increased with the use of occlusive dressings due to greater absorption

4.9 Overdose

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, PLAIN POTENT.

ATC Code: D07AC01

5.1 Pharmacodynamic properties

Betamethasone is a topical corticosteroid with anti-inflammatory antipruritic and antiallergic properties. The cream is water – miscible and suitable for application to moist lesions and to the face, after dermal application it has shown that betamethasone is minimally absorbed from intact or inflamed skin into the human blood circulation.

5.2 Pharmacokinetic properties

Pharmacokinetic investigations after dermal application have shown that betamethasone is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of betamethasone were below the detection limit of 0.001 mcg/ml, suggesting that betamethasone applied topically is unlikely to lead to measurable systemic effects or side effects.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetomacrogol-1000 BP, Cetostearyl alcohol BP, White soft paraffin BP, Liquid paraffin BP, Propylene glycol BP, Chlorocresol BP, Purified Water BP.

6.2 Incompatibilities – N/A



ELYS CHEMICAL INDUSTRIES LIMITED.

ELYVATE CREAM

(Betamethasone 0.1% w/w as Betamethasone Valerate)

Summary of Product Characteristics

6.3 Shelf life: 36 months

6.4 Special precautions for storage

Store below 30°C. Keep out of reach of children.

6.5 Nature and contents of container:

A white, smooth, homogenous cream, in 15gm lacquered, aluminium collapsible tubes with a tamper proof seal at the mouth.

6.6 Special precautions for disposal and other handling- N/A

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Address of Corporate Office:

Elys Chemical Industries Ltd.

Road B, Off Enterprise Road, Opposite Hillock Inn, Industrial Area,
P. O. Box 40411- 00100, GPO, Nairobi, Kenya.

Telephone: +254 (020) 2585031/2/3/4

Telefax Number: +254 (020) 653314

Email: elys@elys.co.ke

Address of Manufacturing Site / Facility:

Elys Chemical Industries Ltd. (Unit 1)

Road B, Off Enterprise Road, Opposite Hillock Inn, Industrial Area,
P. O. Box 40411- 00100, GPO, Nairobi, Kenya.

Telephone: +254 (020) 2585031/2/3/4

Telefax Number: +254 (020) 653314

Email: elys@elys.co.ke



ELYS CHEMICAL INDUSTRIES LIMITED.

ELYVATE CREAM

(Betamethasone 0.1% w/w as Betamethasone Valerate)

Summary of Product Characteristics

8. MARKETING AUTHORISATION NUMBER

Registration Number: 7827

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first authorisation: 09/07/2000

Date of latest renewal: 09/07/2005

10. DATE OF REVISION OF THE TEXT

November 2025