AUSTRALIAN PRODUCT INFORMATION

ELEUPHRAT® (betamethasone dipropionate) Cream, Ointment and Lotion

1 NAME OF THE MEDICINE

Betamethasone dipropionate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone dipropionate equivalent to betamethasone 0.5 mg/g (0.05% w/w).

ELEUPHRAT Cream (0.05% w/w): Each g contains betamethasone dipropionate equivalent to betamethasone 0.5 mg.

ELEUPHRAT Ointment (0.05% w/w): Each g contains betamethasone dipropionate equivalent to betamethasone 0.5 mg.

ELEUPHRAT Lotion (0.05% w/w): Each mL contains betamethasone dipropionate equivalent to betamethasone 0.47 mg.

For the full list of excipients, see **Section 6.1 List of Excipients**.

3 PHARMACEUTICAL FORM

ELEUPHRAT is supplied as cream. ointment, lotion 0.05% w/w.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

ELEUPHRAT is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. These include atopic eczema, infantile eczema, nummular eczema, contact dermatitis, neurodermatitis, anogenital and senile pruritus, lichen planus, intertrigo and psoriasis.

ELEUPHRAT Lotion is indicated wherever hair impedes access to the skin in the treatment of corticosteroid-responsive dermatoses particularly on the scalp, chest and underarms, etc. It is also indicated in the treatment of seborrhoea and psoriasis of the scalp.

4.2 DOSE AND METHOD OF ADMINISTRATION

ELEUPHRAT Cream, Ointment: Apply a small amount to the affected area twice daily. For some patients adequate maintenance therapy may be achieved with once daily application.

ELEUPHRAT Lotion: Apply twice daily. Part the hair with a comb, then apply with nozzle directly on the scalp. Squeeze bottle gently.

In most cases, 4 weeks continuous treatment should be considered the maximum.

Children: Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen.

4.3 CONTRAINDICATIONS

Hypersensitivity to betamethasone dipropionate, other corticosteroids or any components in ELEUPHRAT. Like other topical corticosteroids, ELEUPHRAT preparations are contraindicated in most viral infections of the skin, such as vaccinia, varicella, Herpes simplex, and also tuberculosis and acne rosacea.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

ELEUPHRAT preparations should not be used in or near the eyes.

If irritation or sensitisation develops, treatment should be discontinued and appropriate therapy instituted.

In the presence of an infection, an appropriate antifungal or antibacterial agent should be administered. If a favourable response does not occur promptly, ELEUPHRAT should be discontinued until the infection has been controlled adequately.

Corticosteroids are known to be absorbed percutaneously, therefore in patients under prolonged and extensive topical treatment, the possibility of systemic effects should be kept in mind. This applies particularly when using the occlusive dressing technique.

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children. Patients applying large doses of potent topical corticosteroids over large body surface areas should be evaluated periodically for evidence of HPA axis suppression. Manifestations of Cushing's syndrome also can be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying doses of ELEUPHRAT in excess of 15g per day should be carefully monitored.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of corticosteroid withdrawal may occur, requiring supplemental systemic corticosteroid therapy.

Suitable precautions should be taken when using topical corticosteroids in patients with stasis dermatitis and other skin diseases with impaired circulation.

Topical corticosteroid preparations may produce striae or atrophy of the skin or subcutaneous tissue. If this occurs, treatment should be discontinued.

In most cases, 4 weeks continuous treatment should be considered the maximum.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Use in the elderly

No data available.

Paediatric use

Chronic corticosteroid therapy may interfere with the growth and development of children. Paediatric patients may demonstrate greater susceptibility than mature patients to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects because of greater absorption due to a larger skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilloedema.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No data available.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in Pregnancy (Category B1)

Topical corticosteroids should not be used extensively on pregnant patients in large amounts or for prolonged periods of time.

Use in lactation

Due to lack of data on the safety of betamethasone dipropionate in lactation, care should be exercised to ensure that the potential benefits to the lactating mother outweigh the possible hazards to the nursing infant.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person’s ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

The following adverse reactions have been reported with the use of topical corticosteroids: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

Rarely reported adverse effects include tingling, prickly skin/tightening or cracking of skin, warm feeling, laminar scaling and perilesional scaling, follicular rash, skin atrophy, erythema and telangiectasia.

Systemic adverse reactions, such as vision blurred, have also been reported with the use of topical corticosteroids.

Reporting suspected adverse effects
Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at http://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms: Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism, including Cushing's disease.

Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action
Betamethasone dipropionate is a potent topically-active corticosteroid producing prompt, marked and prolonged anti-inflammatory, anti-pruritic and vasoconstrictive effects.

According to the McKenzie-Stoughton Vasoconstrictor Test, betamethasone dipropionate was demonstrated to be significantly more active ($p<0.05$) than betamethasone valerate, fluocortolone, and flumethasone pivalate. While the direct applicability of this vasoconstrictor test to clinical situations has not been demonstrated conclusively, the results showed betamethasone dipropionate to be active in a concentration of 0.000016%, the lowest concentration tested which showed activity.

Clinical trials
No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption
The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings.

While topical corticosteroids can be absorbed from normal intact skin, dermal inflammation and/or other dermatologic disease processed may increase percutaneous absorption. Occlusive dressings also substantially increase percutaneous absorption.

Distribution

After dermal absorption, topical corticosteroids enter pharmacokinetic pathways similar to those of systemically administered corticosteroids. In varying degrees, corticosteroids are bound to plasma proteins.

Metabolism

Corticosteroids are metabolised primarily in the liver.

Excretion

Corticosteroids are by the kidneys. Some topical corticosteroids and their metabolites undergo biliary excretion.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

ELEUPHRAT Cream (0.05% w/w)
chlorocresol 1 mg/g as preservative
white soft paraffin
liquid paraffin
cetostearyl alcohol
cetomacrogol 1000
monobasic sodium phosphate dihydrate
phosphoric acid
purified water

ELEUPHRAT Ointment (0.05% w/w) white soft paraffin
liquid paraffin

ELEUPHRAT Lotion (0.05% w/w)
isopropyl alcohol
carbomer 934P
sodium hydroxide
purified water

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

The expiry date can be found on the packaging. In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG).

6.4 SPECIAL PRECAUTIONS FOR STORAGE

ELEUPHRAT Cream, Ointment, Lotion: Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

ELEUPHRAT Cream 0.05% w/w (0.5 mg/g): 15 g tubes
ELEUPHRAT Ointment 0.05% w/w (0.5 mg/g): 15 g tubes
ELEUPHRAT Lotion* 0.05% w/w (0.47 mg/mL): 30 mL bottles

** Not available in Australia*

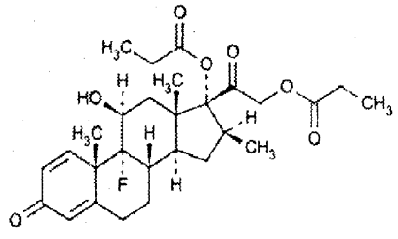
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Betamethasone dipropionate is a white or almost white, crystalline powder, practically insoluble in water, freely soluble in acetone and in methylene chloride, sparingly soluble in ethanol (96 per cent). The chemical name is 9-fluoro-11β-hydroxy-16β-methyl-3,20-dioxopregna-1,4-diene-17,21-diyl dipropanoate. The empirical formula is $C_{28}H_{37}FO_7$. Molecular Weight = 504.6

Chemical Structure



CAS number

5593-20-4

7 MEDICINE SCHEDULE (POISONS STANDARD)

Prescription Only Medicine (Schedule 4)

8 SPONSOR

Organon Pharma Pty Limited
Building A, 26 Talavera Road
Macquarie Park, NSW 2113
Australia

9 DATE OF FIRST APPROVAL

ELEUPHRAT Cream tube AUST R 41865: 22 September 1992
ELEUPHRAT Ointment tube AUST R 144099: 12 November 2007
ELEUPHRAT Lotion bottle AUST R 41866: 22 September 1992

10 DATE OF REVISION

14 January 2021

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
8	Amend Sponsor Details due to transfer of sponsorship

RCN: 000017952-AU