Professional information for ELOZART

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

ELOZART cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 20 mg miconazole nitrate and 10 mg hydrocortisone.

Excipients with known effect:

Chlorocresol 0,1 % *m/m* as a preservative.

Contains butylated hydroxyanisole as an antioxidant.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream for topical administration.

A white, smooth, homogeneous cream free from any visible contaminants.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ELOZART cream is indicated for the treatment of steroid responsive dermatoses, with fungal and bacterial superinfection, e.g. inflammatory, allergic, and pruritic conditions.

Once the inflammatory symptoms have cleared up, treatment may be continued with a miconazole nitrate cream only, if required.

4.2 Posology and method of administration

Posology

Apply once or twice daily by rubbing cream gently into the affected area so that it is completely

absorbed by the skin. Treatment should continue until all signs of the lesion have disappeared – usually after 2 to 5 weeks. (As a precautionary measure application should continue, depending on severity of infection, for 14 days after the lesion has disappeared to avoid relapse.)
If no improvement has occurred after 7 days of application, the patient should be advised to contact their health care professional.

Method of administration

For external use only.

4.3 Contraindications

- Hypersensitivity to miconazole, hydrocortisone or any other ingredient of ELOZART cream (see section 6.1).
- Topical corticosteroid preparations are contraindicated in the treatment of tuberculous skin infections, herpes simplex, vaccinia or varicella.
- Corticosteroids 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, ELOZART cream should not be used during pregnancy.

4.4 Special warnings and precautions for use

Avoid contact with the eyes. Topical corticosteroid preparations should be used with caution in areas around the eyes.
If a secondary microbial skin infection is present, suitable concomitant antimicrobial therapy should be instituted.
Topical corticosteroids should be used with particular caution in facial dermatoses, and only for short periods. ELOZART should not be applied to any skin crease areas.
Care is advised with infants and children when ELOZART is to be applied to extensive surface areas or under occlusive dressings, including baby nappies. Similarly, application to the face should be avoided.
Miconazole administered systemically is known to inhibit CYP3A/2C9, which can lead to

prolonged effects of warfarin or other vitamin K antagonists. While systemic absorption is limited with topical formulations, the concomitant use of ELOZART cream and warfarin or other vitamin K antagonists should be done with caution, and the anticoagulant effect should be carefully monitored and titrated. Patients should be advised of the symptoms of bleeding events and to immediately stop treatment with miconazole and seek medical advice should these symptoms occur.

ELOZART cream contains butylated hydroxyanisole, which may cause local skin reactions such as contact dermatitis, or irritation to the eyes and mucous membranes.

ELOZART cream contains cetostearyl alcohol and chlorocresol, which may cause local skin reactions.

4.5 Interaction with other medicines and other forms of interaction

Miconazole administered systemically is known to inhibit CYP3A/2C9. Due to limited systemic availability after topical application, clinically relevant interactions are rare. However, in patients on warfarin or other vitamin K antagonists, caution should be exercised and anticoagulant effect should be monitored.

4.6 Fertility, pregnancy and lactation

Pregnancy

The use of ELOZART cream during pregnancy is contraindicated.

Breastfeeding

The safety of ELOZART cream during breastfeeding has not been established. Caution is recommended during the lactation period due to the possibility of systemic absorption of topically applied corticosteroids (see 4.8 Undesirable effects).

Fertility

There are no clinical studies with ELOZART cream regarding fertility. No effects are anticipated, since systemic exposure following topical application is negligible.

4.7 Effects on ability to drive and use machines

ELOZART cream applied topically has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Frequency categories:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1 000 to < 1/100)
- Rare (≥ 1/10 000 to < 1/1 000)
- Very rare (< 1/10 000)
- Not known (cannot be estimated from available data).

Infections and infestations	
Not known	Increased susceptibility to infections; masking of infection symptoms during corticosteroid therapy
Immune system disorders	
Uncommon	Application site irritation
Not known	Hypersensitivity reactions, including allergic reactions to any of the ingredients
Endocrine disorders	
Not known	Hypothalamic-pituitary-adrenal axis suppression Adrenal suppression Growth retardation in children Cushingoid state

	Cranial hypertension Steroid rosacea-like facies
Skin and subcutaneous tissue disorders	
Not known	Skin atrophy Thinning of the skin Loss of skin elasticity Telangiectasia Ecchymoses Dilatation of superficial blood vessels Fixed drug eruptions
General disorders and administration site conditions	
Uncommon	Application site burning Application site itching

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 requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

Ingestion of the amounts of the components contained in a tube of cream are unlikely to produce overdosage and toxic effects; however, if accidental ingestion of large quantities of the product occurs, an appropriate method of gastric emptying may be used if considered necessary.

Prolonged and excessive use can result in skin irritation, which usually disappears after discontinuation of therapy.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 13.4.1 Dermatological preparations.

Pharmacotherapeutic group: Corticosteroids with or without anti-infective agents.

ATC code: D01AC.

Miconazole is a broad spectrum antifungal medicine with some antibacterial activity against Gram-positive organisms.

Miconazole inhibits the biosynthesis of ergosterol in fungi and changes the composition of other lipid components in the membrane, resulting in fungal cell necrosis.

Hydrocortisone is a low potency corticosteroid, which on topical application has an effect on inflammatory, allergic and pruritic skin conditions.

5.2 Pharmacokinetic properties

Absorption

Miconazole does not produce detectable blood levels after topical application.

Hydrocortisone penetrates well into the skin and is partially absorbed, depending on the location and type of infection. More than 90 % of the absorbed fraction is bound to plasma proteins.

The metabolism takes place in the liver and tissues, and the metabolites are excreted in the urine, mostly as glucuronides, together with a very small fraction of unchanged hydrocortisone.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetomacrogol ‘1000’, cetostearyl alcohol, chlorocresol, citric acid monohydrate, butylated hydroxyanisole, liquid paraffin, purified water, sodium dihydrogen phosphate and white soft paraffin.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C. Do not refrigerate.

Keep well closed and protected from light.

6.5 Nature and contents of container

ELOZART is packed in printed white aluminium lacquered tubes with white polypropylene piercing caps. One tube is packed in a printed carton.

Pack size: 15 gram or 20 gram.

6.6 Special precautions for disposal and other handling

None.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd

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10 Church Street

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Tel: 087 551 3245

8. REGISTRATION NUMBER

35/13.4.1/0392

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

18 March 2005

10. DATE OF REVISION OF THE TEXT

01 July 2026