

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

TERRA-CORTRIL[®]

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of Terra-Cortril Ointment contains 30mg oxytetracycline as oxytetracycline hydrochloride Ph Eur and 10mg hydrocortisone Ph. Eur

3 PHARMACEUTICAL FORM

Ointment for topical administration.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Terra-Cortril Ointment is indicated in the following disorders: exudative and secondarily infected eczema including atopic eczema, primary irritant dermatitis, allergic and seborrhoeic dermatitis. Secondarily infected insect bite reactions.

In exudative flexural intertrigo Terra-Cortril Ointment can be used for up to seven days.

Like other tetracyclines, oxytetracycline is generally ineffective against *Pseudomonas* and *Proteus* species. Because these are recognised secondary infecting organisms in exudative dermatoses, preliminary identification of the organism and determination of antibiotic sensitivity is important.

4.2 Posology and method of administration

After thorough cleansing of the affected skin areas, a small amount of the ointment should be applied gently. Applications should be made two to four times daily.

Terra-Cortril Ointment is for topical administration only.

Use in the elderly No special precautions.

Use in children Not recommended. (See 'Contra-indications').

Use in renal or hepatic impairment No special precautions.

4.3 Contraindications

Hypersensitivity to one of the components of the preparation.

Primary bacterial infections eg impetigo, pyoderma, furunculosis.

Pregnancy, lactation and in infants and small children because of the theoretical risk of damage to permanent dentition

4.4 Special warnings and precautions for use

Terra-Cortril Ointment should not be continued for more than seven days in the absence of any clinical improvement, since in this situation occult extension of infection may occur due to the masking effect of the steroid.

Extended or recurrent application may increase the risk of contact sensitisation and should be avoided.

The use of oxytetracycline and other antibiotics may result in an overgrowth of resistant organisms - particularly *Candida* and staphylococci. Careful observation of the patient for this possibility is essential. If new infections due to nonsusceptible bacteria or fungi appear during therapy, Terra-Cortril should be discontinued. If extensive areas are treated or if the occlusive technique is used, there may be increased systemic absorption of the corticosteroid and suitable precautions should be taken.

If irritation develops, the product should be discontinued.

Terra-Cortril Ointment is not recommended for ophthalmic use.

The label will state mild steroid.

Topical steroid withdrawal syndrome

Long term 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.

4.5 Interaction with other medicinal products and other forms of interaction

None established.

4.6 Fertility, Pregnancy and lactation

Terra-Cortril Ointment is contra-indicated during pregnancy and in nursing mothers, because of the theoretical risk of damage to permanent dentition.

4.7 Effects on ability to drive and use machines

Terra-Cortril Ointment is not expected to have an influence on the ability to drive or operate machinery.

4.8 Undesirable effects

Hydrocortisone and oxytetracycline are well tolerated by the epithelial tissues and may be used topically with minimal untoward effects. Allergic reactions, including contact dermatitis may occur occasionally, but are rare.

Reactions occurring most often from the presence of the anti-infective ingredients are allergic sensitisations.

The following local side effects have been reported with topical corticosteroids, especially under occlusive dressings; burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria.

The use of Terra-Cortril Ointment should be discontinued if such reactions occur.

Secondary infection The development of secondary bacterial or fungal infection has occurred after use of combinations containing steroids and antimicrobials.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

There is no specific antidote available. In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures.

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Corticosteroids, weak, combinations with antibiotics;
ATC code: D07CA01

The label will state mild steroid.

Terra-Cortril Ointment possesses both the anti-inflammatory activity of hydrocortisone and the broad spectrum antibacterial activity of oxytetracycline, which is active against a wide variety of Gram-positive and Gram-negative organisms.

5.2 Pharmacokinetic properties

Oxytetracycline There is no published information on the systemic absorption of oxytetracycline following dermal application.

Hydrocortisone Following topical steroid application, variable absorption has been reported especially when applied to large surfaces, under occlusive dressing or for prolonged periods of time.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin Ph. Eur., white soft paraffin B.P.

6.2 Incompatibilities

None documented.

6.3 Shelf life

5 Years.

6.4 Special precautions for storage

Store below 25 °C

6.5 Nature and contents of container

Aluminium Tube with screw cap containing 15g ointment.

Aluminium Tube with screw cap containing 30g ointment.

6.6 Special precautions for disposal

None

7. Marketing authorisation holder

Esteve Pharmaceuticals Ltd,
The Courtyard Barns,
Choke Lane,
Cookham
Dean,
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Berkshire,
SL6 6PT,
UNITED KINGDOM.

8 MARKETING AUTHORISATION NUMBER(S)

PL 17509/0075

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/12/1990

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22/03/2024