

Generic Name: Hydrocortisone, Oxytetracycline  
Trade Name: **Terra-Cortril®**  
CDS Effective Date: N/A  
Supersedes: N/A  
Approved by BPOM: February 14, 2018

**PT. PFIZER INDONESIA**  
**Local Product Document**

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**DESCRIPTION**

TERRA-CORTRIL® Ointment contains TERRAMYCIN® brand of oxytetracycline HCl equivalent to 30 mg oxytetracycline per gram of ointment, and 1.0% (10 mg/g) CORTRIL® brand of hydrocortisone in a petrolatum base. Oxytetracycline is a product of the metabolism of *Streptomyces rimosus* and is one of the family of tetracycline antibiotics. Chemically, hydrocortisone is 11b, 17, 21 trihydroxy-pregn-4-ene-3, 20 dione. The empirical formula is C<sub>21</sub>H<sub>30</sub>O<sub>5</sub> and the molecular weight is 362.

**ACTIONS**

TERRA-CORTRIL® Topical Ointment contains both the anti-infective activity of TERRAMYCIN® and anti-inflammatory activity of CORTRIL®.

TERRAMYCIN® is a potent broad-spectrum antibiotic which is useful topically for prevention or treatment of superficial in the cutaneous infections due to a variety of pyogenic bacteria, both gram-positive and gram-negative.

CORTRIL® is primarily effective because of its anti-inflammatory, antipruritic, and vasoconstrictive actions.

In the treatment of superficial infections of the skin amenable to TERRAMYCIN® therapy, the anti-inflammatory actions of the CORTRIL® in this ointment will afford prompt symptomatic relief while the TERRAMYCIN® is acting against the causative organisms.

Where topical therapy with CORTRIL® is of value, the added presence of TERRAMYCIN® will serve to prevent or eradicate secondary bacterial complications. Since varying degrees of bacterial infection frequently complicate those skin conditions for which CORTRIL® topical therapy is indicated, this combined preparation may offer therapeutic advantages over the use of CORTRIL® alone.

TERRA-CORTRIL® Topical Ointment is thus useful in the treatment of skin conditions in which antibacterial and anti-inflammatory effects are desired.

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In the allergic dermatoses, the inciting allergens in the food or environment should be determined and eliminated; patch test, intradermal tests or other suitable procedures should be employed to determine the allergens. In patients with widespread dermatitis, oral therapy with CORTRIL<sup>®</sup> may be advisable.

Supplemental therapy with oral TERRAMYCIN<sup>®</sup> is advisable in the treatment of severe infections or those which may become systemic.

### INDICATIONS

*Cutaneous Infections:* including superficial pyogenic infections, pyoderma pustular dermatitis, and infections associated with minor burns or wound (under close supervision).

*Atopic Dermatitis:* including allergic eczema, both disseminated and circumscribed neurodermatitis, pruritus with lichenifications, eczematoid dermatitis, food eczema, and infantile eczema.

*Contact Dermatitis:* due to plants, drugs, cosmetics, clothing material, and miscellaneous substances.

Only for infected dermatitis or those showing secondary infection. If secondary infection are not already seen it is recommended to have a culture done before use.

### CONTRAINDICATIONS

1. Acute herpes simplex, vaccinia and varicella.
2. Tuberculosis of the skin.
3. Fungal disease of the skin.
4. Hypersensitivity to any of the components of the drug.

### PRECAUTIONS

If irritation develops, the product should be discontinued and appropriate therapy instituted. The use of TERRAMYCIN<sup>®</sup> and other antibiotics may result in an overgrowth of resistant organisms - particularly *Candida* and staphylococci. Constant observation of the patient for this possibility is essential. If new infections due to nonsusceptible bacteria or fungi appear during therapy, appropriate measure should be taken. If favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

If extensive areas are treated or if occlusive technique is used there will be increased systemic absorption of the corticosteroid; suitable precautions should be taken, particularly in children and infants.

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Although topical steroid have not been reported to have an adverse effect on human pregnancy, the safety of their use in pregnant women has not absolutely been established. In laboratory animals, increases in incidence of fetal abnormalities have been associated with exposure of gestating females to topical corticosteroids, in some cases at rather low dosage levels. Therefore, drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of times. The product is not for ophthalmic use.

### **ADVERSE REACTIONS**

CORTRIL® and TERRAMYCIN® are well tolerated by the epithelial tissues and may be used topically, with minimal untoward effects. Allergic reactions may occur occasionally but are rare. The following local adverse reactions have been reported with topical corticosteroids, especially under occlusive dressings.

1. Burnings
2. Itching
3. Irritation
4. Dryness
5. Folliculitis
6. Hypertrichosis
7. Acneform eruptions
8. Hypopigmentation
9. Perioral dermatitis
10. Allergic contact dermatitis
11. Maceration of the skin
12. Secondary infection
13. Skin atrophy
14. Striae
15. Miliaria

The use of TERRA-CORTRIL® Topical Ointment should be discontinued if such reactions occur.

### **DOSAGE AND ADMINISTRATION**

After thorough cleansing of the affected skin areas, a small amount of the ointment should be applied gently. Applications should be made two or four times daily. When actual infection is present, the ointment may be applied on sterile gauze and, by this means, kept in continuous contact with the affected area. Care should be taken not to discontinue therapy too soon after the initial response has been obtained.

### **SUPPLY**

TERRA-CORTRIL® Topical ointment is available in Box, tube of 5 g  
Reg. No. DKL7219809130A1

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STORE IN DRY PLACE BELOW 25°C

HARUS DENGAN RESEP DOKTER

BUKAN UNTUK MATA

Manufactured by

PT. Pfizer Indonesia, Jakarta, Indonesia