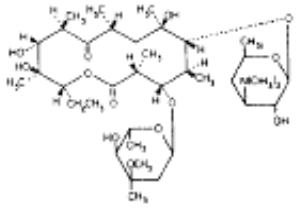
**Rx only.**

# **Staticin®** (erythromycin topical solution) 1.5%

For Dermatologic Use Only - Not for Ophthalmic Use

**DESCRIPTION** - STATICIN Topical Solution contains erythromycin for topical derma-tologic use. Erythromycin is a macrolide antibiotic produced from a strain of *Saccaro-polyspora erythraea* (formerly *Streptomyces erythreus*). It is a base and readily forms salts with acids.

Chemically, erythromycin is $C_{37}H_{67}NO_{13}$. It has the following structural formula:



Erythromycin has the molecular weight of 733.94. It is a white to grayish white or pale yellow crystalline powder.

Each mL of STATICIN contains 15 milligrams of erythromycin in a base of alcohol, propylene glycol, laureth-4 and fragrance.

**CLINICAL PHARMACOLOGY** - The exact mechanism by which erythromycin re-duces lesions of acne vulgaris is not fully known; however, the effect appears to be due in part to the antibacterial activity of the drug.

**MICROBIOLOGY** - Erythromycin acts by inhibition of protein synthesis in susceptible organisms by reversibly binding to 50 *S* ribosomal subunits, thereby inhibiting translo-cation of aminoacyl transfer-RNA and inhibiting polypeptide synthesis. Antagonism has been demonstrated *in vitro* between erythromycin, and lincomycin, chloramphenicol, and clindamycin.

**INDICATIONS AND USAGE** - STATICIN® is indicated for the topical treatment of acne vulgaris.

**CONTRAINDICATIONS** - STATICIN is contraindicated in those individuals who have shown hypersensitivity to any of its components.

**WARNINGS - Pseudomembranous colitis has been reported with nearly all anti-bacterial agents, including erythromycin, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.**

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of "antibiotic-associated colitis."

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial drug clinically effective against *C. difficile* colitis.

**PRECAUTIONS - General:** For topical use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents.

The use of antibiotic agents may be associated with the overgrowth of antibiotic-resistant organisms. If this occurs, discontinue use and take appropriate measures.

Avoid contact with eyes and all mucous membranes.

***Information for Patients:*** Patients using STATICIN should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes, nose, mouth, and all mucous membranes.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. Patients should not use any other topical acne medication unless otherwise directed by their physician.
4. Patients should report to their physician any signs of local adverse reactions.

***Carcinogenesis, mutagenesis, and impairment of fertility:*** No animal studies have been performed to evaluate the carcinogenic and mutagenic potential or effects on fertility of topical erythromycin. However, long-term (2-year) oral studies in rats with erythromycin ethylsuccinate and erythromycin base did not provide evidence of tumorigenicity. There was no apparent effect on male or female fertility in rats fed erythromycin (base) at levels up to 0.25% of diet.

***Pregnancy: Teratogenic effects: Pregnancy category B***: There was no evidence of tera-togenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25% diet) prior to and during mating, during gestation and through weaning of two successive litters.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used in pregnancy only if clearly needed. Erythromycin has been reported to cross the placental barrier in humans, but fetal plasma levels are generally low.

***Nursing women:*** It is not known whether erythromycin is excreted in human milk after topical application. However, erythromycin is excreted in human milk following oral and parenteral erythromycin administration. Therefore, caution should be exercised when

erythromycin is administered to a nursing woman.

***Pediatric use*:** Safety and effectiveness of this product in pediatric patients have not been established.

**Geriatric Use:** Clinical studies of erythromycin topical solution for the treatment of acne vulgaris did not include subjects 65 years of age and older. Other reported clinical experience has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

**ADVERSE REACTIONS** - In controlled clinical trials, the total incidence of adverse reactions associated with the use of STATICIN was approximately 13%. These were dryness (7%), oiliness (2%), pruritus (2%), tenderness (2%), desquamation (2%), erythema (1%) and irritation (1%).

The following additional adverse reactions have been reported occasionally: peeling, generalized urticarial reactions and itching.

**DOSAGE AND ADMINISTRATION** - STATICIN Solution should be applied over the affected area twice a day after the skin is thoroughly washed with warm water and soap and patted dry. Acne lesions on the face, neck, shoulder, chest, and back may be treated in this manner.

This medication should be applied with applicator top. If fingertips are used, wash hands after application. Drying and peeling may be controlled by reducing the frequency of applications.

**HOW SUPPLIED** - STATICIN SOLUTION, 60 mL plastic bottle with optional appli-cator, NDC 0072-8000-60, NSN-6505-01-118-6098.

Store between 15°C and 25°C (59°F and 77°F).

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