

Rx ONLY

Akne-mycin® **(Erythromycin)**

2% TOPICAL OINTMENT FOR ACNE

FOR EXTERNAL USE ONLY

DESCRIPTION: Akne-mycin (erythromycin) topical ointment contains erythromycin which is produced from a strain of *Streptomyces erythraeus*. Each gram of Akne-mycin topical ointment contains 20 mg of erythromycin base in a vehicle consisting of mineral oil, petrolatum, paraffin, talc, titanium dioxide, trilaureth 4 phosphate, oleyl oleate, tricetareth 4 phosphate, cetostearyl alcohol and sorbitol. Akne-mycin marketed in the United States is not of the same composition as Akne-mycin marketed in Europe.

CLINICAL PHARMACOLOGY: Although the mechanism by which Akne-mycin acts in reducing the inflammatory lesions of acne vulgaris is unknown, it is presumably due to the antibiotic action of the drug.

INDICATIONS AND USAGE: Akne-mycin is indicated for topical control of acne vulgaris.

CONTRAINDICATIONS: Akne-mycin is contraindicated in persons who have shown hypersensitivity to erythromycin or to any of the other listed ingredients.

WARNINGS: The safe use of Akne-mycin during pregnancy or lactation has not been established.

PRECAUTIONS: Akne-mycin is for topical use only and should be kept out of the eyes, nose and mouth.

The use of antibiotic agents may be associated with the overgrowth of antibiotic resistant organisms. If this occurs, administration of the drug should be discontinued and appropriate measures taken.

ADVERSE REACTIONS: In clinical trials there was one report of a possible contact sensitization which could not be confirmed. There were isolated reports of skin irritation, such as erythema and peeling.

DOSAGE AND ADMINISTRATION: Akne-mycin should be applied to the affected area twice daily, morning and evening.

HOW SUPPLIED: Akne-mycin is supplied in a 25 gram sealed tube. Store below 27°C (80°F).

Distributed by:

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