SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

ILOTYCIN T.S. (solution)

COMPOSITION

Each 1 ml solution of ILOTYCIN T.S. contains 20 mg of erythromycin base.

Excipients:

Alcohol, propylene glycol

Contains alcohol 66,5 % *v/v*

CATEGORY AND CLASS

A 20.1.6 Topical antibiotics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Erythromycin is a broad spectrum antibiotic produced from a strain of *Streptomyces erythraeus* and belongs to the macrolide group of antibiotics. It is basic and readily forms salts with acids.

Erythromycin inhibits bacterial protein synthesis without affecting nucleic acid synthesis.

INDICATIONS

ILOTYCIN T.S. is indicated for the treatment of the following grades of acne vulgaris (primary grades II and III) in which comedones, papules and pustules predominate.

This preparation is not recommended for deep, cystic nodular varieties (acne conglobata).

CONTRAINDICATIONS

ILOTYCIN T.S. is contraindicated in patients with a history of hypersensitivity to erythromycin.

WARNINGS AND SPECIAL PRECAUTIONS

ILOTYCIN T.S. is for external use only. ILOTYCIN T.S. should not be used in the eyes. Do not let the solution get into the eyes.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

Usage in pregnancy: The safety of ILOTYCIN T.S. in pregnant women has not been established.

DOSAGE AND DIRECTIONS FOR USE

ILOTYCIN T.S. should be applied to the affected area twice a day after the skin is thoroughly washed with warm water and soap. Apply ILOTYCIN T.S. over entire facial area using the “Dab-O-Matic” applicator.

Acne lesions on the neck, shoulder, chest and back may also be treated in this manner.

SIDE EFFECTS

The use of antimicrobial medicines may be associated with the overgrowth of antibiotic-resistant organisms; in such a case, antibiotic administration should be stopped and appropriate measures taken.

As with any other medicine intended for topical use, there is always the possibility that primary irritation or allergic contact dermatitis will develop in certain individuals. However, previous experience with ointment preparations of ILOTYCIN indicates that such occurrences are rare, and the incidence with this formulation is less than 1 %.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Not known.

IDENTIFICATION

A brilliantly clear, colourless solution with a strong alcoholic odour.

PRESENTATION

50 ml is packed in an opaque, white high density polyethylene bottle sealed with an opaque white polypropylene screw cap together with a white opaque applicator dabber with a white spiral.

STORAGE INSTRUCTIONS

Store at or below 25 °C in tightly closed containers.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

M/20.1.6/80

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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