

RetabacTM

Retapamulin

COMPOSITION

RetabacTM Ointment: Each gram ointment contains Retapamulin INN 10 mg.

PHARMACOLOGY

Retapamulin is a semisynthetic derivative of the compound pleuromutilin. In vitro activity of Retapamulin against isolates of *Staphylococcus aureus* as well as *Streptococcus pyogenes* has been demonstrated. Retapamulin selectively inhibits bacterial protein synthesis by interacting at a site on the 50S subunit of the bacterial ribosome through an interaction that is different from that of other antibiotics. This binding site involves ribosomal protein L3 and is in the region of the ribosomal P-site and peptidyl transferase center. By virtue of binding to this site, pleuromutilins inhibit peptidyl transfer, block P-site interactions and prevent the normal formation of active 50S ribosomal subunits. Retapamulin demonstrates no in vitro target-specific cross-resistance with other classes of antibiotics.

INDICATION

RetabacTM is indicated for use in adults and pediatric patients (aged 9 months and older) for the topical treatment of following skin infections due to *Staphylococcus aureus* or *Streptococcus pyogenes*.

- Impetigo
- Secondary skin infections: Infected dermatitis, infected traumatic lesions (e.g. small lacerations, sutured wounds, cuts, abrasions etc.)

DOSAGE AND ADMINISTRATION

A thin layer of **RetabacTM** should be applied to the affected area twice daily for 5 days (up to 100 cm² in total area in adults or 2% total body surface area in pediatric patients). The treated area may be covered with a sterile bandage or gauze dressing if desired.

CONTRAINDICATION

None

WARNING AND PRECAUTION

- In the event of sensitization or severe local irritation, usage should be discontinued.
- Not intended for ingestion or for oral, intranasal, ophthalmic, or intravaginal use.

ADVERSE EFFECT

Application site irritation ($\leq 2\%$ of patients may experience).

DRUG INTERACTION

The effect of concurrent application of Retapamulin and other topical products to the same area of skin has not been studied.

USE IN PREGNANCY AND LACTATION

Pregnancy Category B. It is not known whether Retapamulin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

STORAGE

Store in a cool (below 25⁰ C) and dry place protected from light. Keep out of the reach of children.

HOW SUPPLIED

RetabacTM Ointment: Each pack has an aluminium tube containing 10 gm ointment.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH