AVOBAN OINTMENT

Avalon Pharma

Mupirocin Ointment, 2% For Dermatologic Use

Microbiology:

Avoban Mupirocin is an antibacterial agent produced by fermentation using the organism Pseudomonas fluorescens. Its spectrum of activity includes gram-positive bacteria. It is also active, *in vitro* only, against certain gram-negative bacteria. Mupirocin inhibits bacterial protein synthesis by reversibly and specifically binding to bacterial isoleucyl transfer-RNA synthetase. Due to this unique mode of action, mupirocin does not demonstrate cross-resistance with other classes of antimicrobial agents.

Avoban Mupirocin has been shown to be active against susceptible strains of *Staphylococcus aureus* and *Streptococcus pyogenes*, both *in vitro* and in clinical studies.

INDICATIONS AND USAGE

Avoban Mupirocin Ointment, 2% is indicated for the topical treatment of impetigo due to: *Staphylococcus aureus* and *Streptococcus pyogenes*.

CONTRAINDICATIONS

This drug is contraindicated in individuals with a history of sensitivity reactions to any of its components.

WARNINGS

Avoban Mupirocin Ointment, 2% is not for ophthalmic use.

PRECAUTIONS

If a reaction suggesting sensitivity or chemical irritation should occur with the use of Mupirocin Ointment, 2%, treatment should be discontinued and appropriate alternative therapy for the infection instituted.

Drug Interactions:

The effect of the concurrent application of Mupirocin Ointment, 2% and other drug products is unknown.

Pregnancy

Pregnancy Category B:

There are, however, no adequate and well-controlled studies in pregnant women.

Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers:

It is not known whether this drug is excreted in human milk drugs are excreted in human milk, caution should be exercised when Mupirocin Ointment, 2% is administered to a nursing woman.

Pediatric Use:

The safety and effectiveness of Mupirocin Ointment, 2% have been established in the age range of 2 months to 16 years. Use of Mupirocin Ointment, 2% in these age groups is supported by evidence from adequate and well-controlled studies of Mupirocin Ointment, 2% in impetigo in pediatric patients studied as a part of the pivotal clinical trials.

ADVERSE REACTIONS

The following local adverse reactions have been reported in connection with the use of Avoban Mupirocin Ointment, 2%: application site reactions and pruritus, each in 1% of patients; contact dermatitis and furunculosis, each in 0.7% of patients; and exfoliative dermatitis and rash, each in 0.3% of patients.

DOSAGE AND ADMINISTRATION

A small amount of Avoban Mupirocin Ointment, 2% should be applied to the affected area three times daily. The area treated may be covered with a gauze dressing if desired. Patients not showing a clinical response within 3 to 5 days should be re-evaluated.

HOW SUPPLIED

Avoban Ointment, 2% is supplied in 15 gram, tube. Store at controlled room temperature 20° to 25°C