

To be sold on the prescription of a registered physician only

## COMPOSITION

Each gram of **Bactoken®** 2% Ointment contains the active Mupirocin USP 20 mg.

## PHARMACOLOGY

Mupirocin is a naturally occurring antibiotic produced by fermentation using the organism *Pseudomonas fluorescens*. It exhibits antibacterial activity against pathogens commonly associated with skin infections, including *Staphylococcus aureus* (including methicillin-resistant *Staphylococcus aureus* – **MRSA**), other *staphylococci*, *streptococci*, and certain gram-negative organisms such as *Escherichia coli* and *Haemophilus influenzae*.

Mupirocin inhibits bacterial protein synthesis by reversibly and specifically binding to bacterial isoleucyl transfer-RNA synthetase. This unique mechanism of action results in no in vitro cross-resistance with other classes of antimicrobial agents. Mupirocin is bactericidal at concentrations achieved through topical application. However, the minimum bactericidal concentration (MBC) is generally eight- to thirty-fold higher than the minimum inhibitory concentration (MIC).

## INDICATION

**Bactoken®** 2% Ointment is indicated for the topical treatment of primary and secondary skin infections, including:

- Folliculitis (infected hair follicles with pus-filled pimples)
- Impetigo (superficial skin infection with blistering and crusting)
- Furunculosis (recurring boils)
- Other skin infections caused by mupirocin-susceptible organisms, including MRSA

**Note:** This ointment is for external use only.

## DOSAGE AND ADMINISTRATION

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

## CONTRAINDICATION

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

## PRECAUTION

- Not for ophthalmic (eye) or intranasal (inside the nose) use.
- Discontinue use if signs of irritation or allergic reaction appear and initiate alternative therapy.
- Prolonged use may result in the overgrowth of nonsusceptible organisms, including fungi.
- Avoid contact with eyes, especially when applied on the face.
- The polyethylene glycol base may be absorbed through broken skin or wounds and is excreted via the kidneys. Avoid use on large areas of damaged skin in patients with moderate to severe renal impairment.

## DRUG INTERACTION

The effect of the concurrent application of Mupirocin and other drug products has not been studied.

## USE IN PREGNANCY

The drug is classified in Pregnancy Category B. Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

## USE IN LACTATION

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

## PEDIATRIC USE

The safety and effectiveness of Mupirocin have been established in the age range of 2 months to 16 years. Use of the ointment in these age groups is supported by evidence from adequate and well-controlled studies of Mupirocin in impetigo in pediatric patients.

## Driving and using machines

It is unlikely that **Bactoken®** will affect your ability to drive or operate machinery.

## MISSED DOSE INSTRUCTIONS

- Apply the missed dose as soon as remembered.
- If the next dose is due within an hour, skip the missed dose.
- Do not use a double dose to make up for a missed one.

## STOPPING THE TREATMENT

Do not stop using Bactoken® without consulting a doctor. Stopping too early may lead to incomplete treatment and bacterial regrowth.

## ADVERSE EFFECT

The following local adverse reactions have been reported in connection with the use of Mupirocin Ointment: burning, stinging, or pain in 1.5% of patients; itching in 1% of patients; rash, nausea, erythema, dry skin, tenderness, swelling, contact dermatitis, and increased exudate in less than 1% of patients.

## STORAGE

Store below 25°C. in dry place. Keep away from light. Keep out of reach of children.

## HOW SUPPLIED

**Bactoken® 2% Ointment:** Box containing 10/15/ 20 gm ointment in a laminated tube.

Manufactured by :



**SQUARE  
PHARMACEUTICALS PLC.**  
Saidgaria, Pabna, Bangladesh

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