Summary of Product Characteristics

1. Name of the medicinal product

Bactrocin Ointment

2. Qualitative and quantitative composition

Each gm ointment contains Mupirocin USP 20.0 mg.

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Ointment.

A white homogenous greasy ointment filled and sealed in printed laminated tube with white color cap.

4. Clinical particulars

4.1 Therapeutic indications

Bactrocin Ointment is indicated for the topical treatment of impetigo due to:
Staphylococcus aureus and *Streptococcus pyogenes*

4.2 Posology and method of administration

A small amount of Ointment should be applied to the affected area. 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.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Mupirocin ointment is not for ophthalmic or intra-nasal use. If a reaction suggesting sensitivity or chemical irritation should occur with the use of Mupirocin ointment, treatment should be discontinued and appropriate alternative therapy for the infection instituted. As with other antibacterial products, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. When Mupirocin is used on the face care should be taken to avoid the eyes. Polyethylene Glycol can be absorbed from open wounds and damaged skin and is secreted by the kidneys. In common with other polyethylene glycol-based ointments, Mupirocin ointment should not be used in conditions where absorption of large quantities of polyethylene glycol is possible, especially if there is

evidence of moderate or severe renal impairment.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy, and lactation

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 the drug is administered to a nursing woman.

4.7 Effects on ability to drive and use machines.

No adverse effects on the ability to drive or operate machinery have been identified.

4.8 Undesirable effects

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.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Symptoms and signs

There is currently limited experience with over dosage of mupirocin.

Treatment

There is no specific treatment for an overdose of mupirocin. In the event of overdose, the patient should be treated supportively with appropriate monitoring as necessary. Further management should

be as clinically indicated or as recommended by the national poisons center, where available.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibiotics and chemotherapeutics for dermatological use. ATC code: D06AX09

Mechanism of action

Mupirocin is a naturally occurring antibiotic. It is an antibacterial agent produced by fermentation using the organism Pseudomonas fluorescens. It is active against a wide range of bacteria those responsible for the majority of skin infections, e.g. *Staphylococcus aureus* including methicillin-resistant *Staphylococcus aureus* (MRSA) other staphylococci and streptococci. It is also active against certain gram-negative pathogens, like Escherichia coli and *Haemophilus influenza*.

5.2 Pharmacokinetic properties

After topical application of Ointment, mupirocin is only very minimally absorbed systemically and that which is absorbed is rapidly metabolised to the antimicrobially inactive metabolite, monic acid. Penetration of mupirocin into the deeper epidermal and dermal layers of the skin is enhanced in traumatised skin and under occlusive dressings.
Elderly patients
No restrictions unless there is evidence of moderate or severe renal impairment.

5.3 Preclinical safety data

Pre-clinical effects were seen only at exposures which are extremely unlikely to cause concern for humans under normal conditions of clinical use. Mutagenicity studies revealed no risks to man.

6. Pharmaceutical particulars

6.1 List of excipients

Macrogol 400 (Polyethylene Glycol 400)
Macrogol 4000 (Polyethylene Glycol 4000)
Chlorocresol
Propylene Glycol
Lavender Oil

6.2 Incompatibilities

None stated

6.3 Shelf life

2 Years (24 Months)

6.4 Special precautions for storage:

Store below 30°C and protect from light. Do not freeze. Keep out of the reach of children.

6.5 Nature and contents of container

Laminated tube

6.6 Special precautions for disposal and other handling:

Any product remaining at the end of treatment should be discarded.
Any unused medicinal product or waste material should be disposed of accordance with local requirements. Wash your hands after application.

7. Marketing authorization holder and manufacturing site addresses

Marketing Authorization Holder

Square Pharmaceuticals Ltd. Square Centre

48, Mohakhali C.A, Dhaka – 1212, Bangladesh.

Manufacturing Site Address

Square Pharmaceuticals Ltd. Square Road,

Salgaria, Pabna 6600 Bangladesh.

8. Marketing authorization number

H2025/CTD9523/21661

9. Date of first registration

April 2025

10. Date of revision of the text:

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