Summary of Product Characteristics for Pharmaceutical Products

1. Name of medicinal product

Mupirocin 2% Ointment

2. Qualitative and quantitative composition

Mupirocin USP: 2.0 % w/w
Water soluble base: q.s.
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Ointment

4. Clinical particulars

4.1 Therapeutic indications

Mupirocin Ointment is a topical antibacterial agent, active against those organisms responsible for the majority of skin infections, e.g. *Staphylococcus aureus*, including methicillin-resistant strains, other staphylococci, streptococci. It is also active against Gramnegative organisms such as *Escherichia coli* and *Haemophilus influenzae*. Mupirocin Ointment is used for skin infections, e.g. impetigo, folliculitis, furunculosis.

4.2 Posology and Method of Administration

Posology
*Adults (including elderly/ hepatically impaired) and children***:**
Two to three times a day for up to ten days, depending on the response.

Renally impaired
See section 4.4.

Method of Administration:
For topical administration.

A small quantity of Mupirocin Ointment should be applied to cover the affected area. The treated area may be covered by a dressing.

Any product remaining at the end of treatment should be discarded.

Do not mix with other preparations as there is a risk of dilution, resulting in a reduction of the antibacterial activity and potential loss of stability of the mupirocin in the ointment.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. This Mupirocin Ointment formulation is not suitable for ophthalmic or intranasal use.

4.4 Special Warnings and Precautions for Use

Should a possible sensitisation reaction or severe local irritation occur with the use of Mupirocin Ointment, treatment should be discontinued, the product should be washed off and appropriate therapy instituted.

As with other antibacterial products, prolonged use may result in overgrowth of nonsusceptible organisms.

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. Although this is less likely to occur with topically applied mupirocin, if prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

Renal impairment:

Polyethylene glycol can be absorbed from open wounds and damaged skin and is excreted 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.

Mupirocin Ointment is not suitable for:

- ophthalmic use
- intranasal use
- use in conjunction with cannulae and - at the site of central venous cannulation.

Avoid contact with the eyes. If contaminated, the eyes should be thoroughly irrigated with water until the ointment residues have been removed.

4.5 Interaction with other medicinal products and other forms of interaction

No drug interactions have been identified.

4.6 Pregnancy and lactation

Fertility:
There are no data on the effects of mupirocin on human fertility. Studies in rats showed no effects on fertility.

Pregnancy:
Reproduction studies on mupirocin in animals have revealed no evidence of harm to the foetus. As there is no clinical experience on its use during pregnancy, mupirocin should only be used in pregnancy when the potential benefits outweigh the possible risks of treatment.

Breast-feeding:
There is no information on the excretion of mupirocin ointment in milk. If a cracked nipple is to be treated, it should be thoroughly washed prior to breast feeding.

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

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000), including isolated reports.

Common and uncommon adverse reactions were determined from pooled safety data from a clinical trial population of 1573 treated patients encompassing 12 clinical studies. Very rare adverse reactions were primarily determined from post-marketing experience data and therefore refer to reporting rate rather than true frequency.

Immune system disorders:
Very rare: Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema have been reported with have been reported with Mupirocin ointment.

Skin and subcutaneous tissue disorders:
Common: Burning localised to the area of application.
Uncommon: Itching, erythema, stinging and dryness localised to the area of application. Cutaneous sensitisation reactions to mupirocin or the ointment base.

Reporting of suspected adverse reactions

Healthcare professionals are requested to report any suspected adverse reactions via national regulatory portal or systems.

4.9 Overdose

Symptoms and signs
There is currently limited experience with overdosage 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 centre, where available.

5. Pharmacological properties

5.1 Pharmacodynamic properties

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

Mode of Action
Mupirocin is a novel antibiotic produced through fermentation by *Pseudomonas fluorescens*. Mupirocin inhibits isoleucyl transfer-RNA synthetase, thereby arresting bacterial protein synthesis.

Mupirocin has bacteriostatic properties at minimum inhibitory concentrations and bactericidal properties at the higher concentrations reached when applied locally.

Mechanism of Resistance
Low-level resistance in staphylococci is thought to result from point mutations within the usual staphylococcal chromosomal gene (ileS) for the target isoleucyl tRNA synthetase enzyme. High-level resistance in staphylococci has been shown to be due to a distinct, plasmid encoded isoleucyl tRNA synthetase enzyme.

Intrinsic resistance in Gram negative organisms such as the *Enterobacteriaceae* could be due to poor penetration of the outer membrane of the Gram-negative bacterial cell wall. Due to its particular mode of action, and its unique chemical structure, mupirocin does not show any cross-resistance with other clinically available antibiotics.

Microbiological Susceptibility
The prevalence of acquired resistance may vary geographically and with time for selected species, and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice

should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infection is questionable.

Commonly susceptible species
*Staphylococcus aureus**
*Streptococcus pyogenes**
Streptococcus spp. (β-haemolytic, other than *S. pyogenes*)
Species for which acquired resistance may be a problem
Staphylococcus spp., coagulase negative
Inherently resistant organisms
Corynebacterium spp.
Micrococcus spp.

* Activity has been satisfactorily demonstrated in clinical studies

5.2 Pharmacokinetic properties

After topical application of mupirocin 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 use. Mutagenicity studies revealed no risks to man.

6. Pharmaceutical particulars
6.1 List of excipients
P.E.G.400/Macrogol 400, P.E.G.4000/Macrogol 4000.

6.2
Incompatibilities
Not Applicable.

6.3 Shelf life
18 Months

6.4 Special precautions for storage
Store below 30°C. Do not freeze.

6.5 Nature and contents of container
A printed carton containing a leaflet and a printed aluminum collapsible tube containing a white semi solid ointment.

6.6 Special precautions for disposal No special requirements.

7. Marketing Authorization Holder
Glenmark Pharmaceuticals Ltd.
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8. Marketing Authorization Number
13440

9. Date of first authorization/renewal of the authorization
2/4/2026

10. Date of revision of the text
1/4/2026