
MUPIROCIN OINTMENT USP 2.0% W/W

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of medicinal product

Mupirocin Ointment USP 2.0% w/w

2. Composition:

Mupirocin USP 2%

In a non-greasy base q.s.

3. Pharmaceutical Form:

Topical

4. Clinical Particulars

4.1 Indication

Mupirocin 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 Gram-negative organisms such as *Escherichia coli* and *Haemophilus influenzae*. Mupirocin Ointment is used for skin infections, e.g. impetigo, folliculitis, furunculosis.

4.2 Posology and Administration

Mupirocin Ointment should be applied to the affected area up to three times a day for up to 10 days. The area may be covered with a dressing or occluded if desired.

4.3 Contraindication

Hypersensitivity to the active substance(s) or to any of the excipients.

4.4 Special Warning & 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 non-susceptible 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 (in neonates or infants);

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- use in conjunction with cannulae;
- at the site of central venous cannulation.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies found.

4.6 Fertility, Pregnancy and lactation

Mupirocin Ointment should only be used in pregnancy when the potential benefits outweigh the possible risks of treatment.

4.7 Effects on ability to drive and use machines

Mupirocin 2% w/w Ointment has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema have been reported with Mupirocin Ointment.

4.9 Overdose

Symptoms There is currently limited experience with overdosage of mupirocin.

Management

The toxicity of mupirocin is very low. In the event of accidental ingestion of the ointment, symptomatic treatment should be given. In case of erroneous oral intake of large quantities of the ointment, renal function should be closely monitored in patients with renal insufficiency because of the possible side effects of polyethylene glycol. 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

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.

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.

6. Shelf Life

24 months

7. Special precaution for Storage

Do not store above 30°C.

8. Nature and contents of container

15 gm tube packed in carton along with insert.

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9. Marketing Holder

YOGI CARE PHARMACEUTICAL PRIVATE LIMITED

OFFICE-1113,1114, BINORI B SQUARE - 3, SINDHU BHAVAN

ROAD, NR. TRADE BULLS, Bodakdev, Ahmedabad, Ahmedabad,

Gujarat, 380054

10. Manufacturer

SPENSUS PHARMACEUTICALS PRIVATE LIMITED

Unit No. 1, survey No. 284, Ganeshpura, Gujarat - 382705