For the use of a Registered Medical Practitioner or Hospital or a Laboratory.

MUODERM

Mupirocin 2%w/w Ointment

Active Ingredient: Mupirocin BP
Excipient: Macrogol 400, and Macrogol 3350.
Dosage Form: Topical Ointment
Product Description: White or almost white Ointment.
Pharmacodynamics:
Pharmacotherapeutic group: Antibiotics and chemotherapeutics for topical use, ATC code: D06AX09
Mechanism 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.
Pharmacokinetics:
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.
Indication: Mupirocin Ointment is used for bacterial skin infections, e.g. impetigo, folliculitis, furunculosis.
Recommended Dose:
Adults and Children:

MUODERM should be applied to the affected area 2 to 3 times a day for up to 10 days, depending on the response. The area may be covered with a dressing or occluded if desired. 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.
Route of Administration: Topical (External Preparation).

Contraindication: Patients with known hypersensitivity to the active substance mupirocin or to any of the excipients

Warning & Precautions:

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 (in neonates or infants);
- Use in conjunction with cannula;
- 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.

Interactions with other medicaments: Not known.

Pregnancy and Lactation:

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 Ointment should only be used in pregnancy when the potential benefits outweigh the possible risks of treatment. It is unknown whether mupirocin is excreted in human milk. If a cracked nipple is to be treated, it should be thoroughly washed prior to breast-feeding.

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

Side Effect:

The most common side effects are numbness and a stinging feeling in the mouth. Oral numbness (hypoesthesia) and a stinging feeling in the mouth (oral pain) are uncommon. Less than 1 in 10000 may have Laryngospasm or bronchospasm. Less than 1 in 10000 may have hypersensitivity reactions which may be associated with pruritus, urticaria, photosensitivity reaction and rash. Anaphylactic reaction which can be potentially life-threatening are not known so far. Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

Symptoms and Treatment of 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.

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

Instruction for Use: MUODERM should be applied to the affected area 2 to 3 times a day for up to 10 days, depending on the response. The area may be covered with a dressing or occluded if desired. 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. Any ointment remaining at the end of treatment should be discarded. Wash your hands after application.

Storage Condition: Store below 30°C, Do not freeze and replace cap tightly after use.

Shelf Life: 36 months from date of manufacture.

Therapeutic Code: ATC code: D06AX09

Presentation: 15g of Aluminum tube with cap, such single tube packed in one carton along with package insert.

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Manufacturer:
ICPA Health Products Limited
286/287/288, GIDC, Ankleshwar,
Gujarat, 393002, India.

Product registration holder:
Healol Pharmaceuticals Sdn Bhd,
74-3, Jalan Wangsa Delima 6,
KLSC Wangsa Maju, 53300,
Kuala Lumpur, Malaysia.

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