Important information. Please read carefully.

EPIROZIN OINTMENT
Mupirocin 2% w/w

COMPOSITION
Contains Mupirocin 2% w/w (as Mupirocin Calcium).

PHARMACODYNAMICS
Pharmacotherapeutic group: Antibiotics and chemotherapeutics for dermatological 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.

Commonly susceptible species:
Staphylococcus aureus, Streptococcus pyogenes*, Streptococcus* spp. (β-haemolytic, other than *S.pyogenes*)
*Activity has been satisfactorily demonstrated in clinical studies.

Species for which acquired resistance may be a problem:
Staphylococcus spp., coagulase negative.

Inherently resistant organisms:
Corynebacterium spp., *Micrococcus* spp.

PHARMACOKINETICS
After topical application of Epirozin 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.

INDICATIONS
Epirozin Ointment is indicated for the treatment of bacterial skin infections eg. impetigo, folliculitis and furunculosis.

DOSAGE AND ADMINISTRATION
Adults and Children:
Apply 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.

CONTRAINDICATIONS
Epirozin Ointment should not be given to patients with history of hypersensitivity to mupirocin or any of the excipients.
This Epirozin Ointment formulation is not suitable for ophthalmic or intranasal use.

WARNINGS AND PRECAUTIONS
Should a possible sensitisation reaction or severe local irritation occur with the use of Epirozin 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.

Epirozin 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.

DRUG INTERACTIONS
No drug interactions have been identified.

PREGNANCY AND LACTATION
Pregnancy: Reproduction studies on Mupirocin ointment in animals have revealed no evidence of harm to the fetus. As there is no clinical experience on its use during, Epirozin Ointment should only be used in pregnancy when the potential benefits outweigh the possible risks of treatment.

Lactation: There is no information on the excretion of Epirozin Ointment in milk. If a cracked nipple is to be treated, it should be thoroughly washed prior to breast feeding.

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

SIDE EFFECTS
Immune system disorders:
Very rare: Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema have been reported with Epirozin 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 sensitization reactions to Mupirocin or the ointment base.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE
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.

EFFECT ON ABILITY TO DRIVE AND USE MACHINES
No adverse effects on the ability to drive or operate machinery have been identified.

INSTRUCTION FOR USE
Epirozin Ointment 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 the treatment should be discarded.

Wash your hands after application.

STORAGE CONDITION
Store below 30°C.

SHELF LIFE
The expiry date is indicated on the packaging.

PRODUCT DESCRIPTION, DOSAGE FORM AND PACKAGING AVAILABLE
Translucent, smooth and homogeneous ointment.

Epirozin Ointment is available in 15g of Aluminium collapsible tube with cap in a cardboard box with product leaflet.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

For further information, please consult your physician or pharmacist.
Revision Date: 27-Aug-2025

Manufacturer and Product Registration Holder:
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EPxxxx-001 08.25

Font Size: 10 (For registration purpose)