Epirozin Ointment

Mupirocin Ointment 2% w/w

COMPOSITION

Contains Mupirocin Calcium equivalent to 2% w/v mupirocin.

PHARMACODYNAMICS

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 and streptococci. It is also active against gram-negative pathogens e.g. *Haemophilus influenzae*.

PHARMACOKINETICS

Mupirocin penetrates intact human skin but rate of systemic absorption appears to be low. Systemically absorbed mupirocin is rapidly metabolized to the inactive metabolite monic acid and quickly excreted by the kidneys.

INDICATIONS

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

DOSAGE AND ADMINISTRATION

For external use only. Adult 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. There is no long-term experience of mupirocin in humans.

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

CONTRAINDICATIONS

Epirozin Ointment should not be given to patients with a history of hypersensitivity to mupirocin or any of the excipients.

WARNINGS AND PRECAUTIONS

Mupirocin is not suitable for ophthalmic or intranasal use. When used on the face, care should be taken to avoid the eyes. Should a possible sensitisation reaction or severe local irritation occur, treatment should be discontinued, the product should be washed off and appropriate alternative therapy for the infection instituted.

As with other antibacterial products, prolonged use may result in overgrowth of non-susceptible organisms.

Mupirocin has not been studied in infants under 1 year old and therefore it should not be used in these patients until further data become available.

Polyethylene glycol in the ointment can be absorbed from open wounds and damaged skin and is excreted by the kidneys. Should be used with caution if there is evidence of moderate or severe renal impairment.

DRUG INTERACTIONS

No drug interactions have been identified.





PREGNANCY AND LACTATION

Studies in experimental animals have shown mupirocin to be without teratogenic effects. However, there is inadequate evidence of safety to recommend the use during pregnancy. Adequate human and animal data on use during lactation are not available.

SIDE EFFECTS

Adverse reactions are itching, erythema, stinging, burning and dryness localised to the area of application. Cutaneous sensitisation reactions and systemic allergic reactions have been reported rarely.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE

The toxicity of mupirocin is very low. In the event of accidental ingestion or overdosage, symptomatic treatment should be given.

STORAGE CONDITION

Store below 30°C.

SHELF LIFE

The expiry date is indicated on the packaging.

PRODUCT DESCRIPTION

White to off-white, translucent, smooth, homogenous and water soluble ointment in aluminium collapsible tube of 15g and 5g.

INSTRUCTIONS FOR USE/HANDLING

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

LIST OF EXCIPIENTS

Polyethylene Glycol 400, Polyethylene Glycol 4000.

KEEP OUT OF REACH OF CHILDREN/ JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

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Manufactured and Marketed By **Xepa-Soul Pattinson (Malaysia) Sdn Bhd** 1-5 Cheng Industrial Estate, 75250, Melaka, Malaysia.

Product Registrant Apex Pharma Marketing Pte. Ltd.

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