

MCIAN
Mupirocin Ointments USP 2%

QUALITATIVE AND QUANTITATIVE COMPOSITION:

Label claim:

Composition:
Mupirocin USP 2% w/w
Ointment base q.s.

List of Excipients:

Light Liquid paraffin BP
White Soft Paraffin BP
Hard Paraffin BP
Chlorocresol BP
Propylene Glycol BP

INDICATION:

Mcian 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*.

Mcian Ointment is used for skin infections, e.g. impetigo, folliculitis, furunculosis.

PHARMACEUTICAL FORM:

A off-white coloured semisolid mass filled in 5 gm laminated tube and packed in a printed

DOSAGE AND ADMINISTRATION:

Posology

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

Method of Administration: For topical administration.

CONTRAINDICATION:

Hypersensitivity to the active substance or to any of the excipients
This Mcian Ointment formulation is not suitable for ophthalmic or intranasal use.

SPECIAL WARNING AND PRECAUTION FOR USE:

Should a possible sensitisation reaction or severe local irritation occur with the use of Mcian 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 Ointments USP 2% 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.

Mcian 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.

ADVERSE REACTION:

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, <1/10000), very rare (<1/10,000), including isolated reports.

Immune system disorders:

Very rare: Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema have been reported with Mcian 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.

INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:

No drug interactions have been identified.

PREGNANCY AND LACTATION:

Pregnancy

Reproduction studies on Mcian in animals have revealed no evidence of harm to the foetus. As there is no clinical experience on its use during pregnancy, Mcian 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 Mcian 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 mupirocin on human fertility. Studies in rats showed no effects on fertility

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

No adverse effects on the ability to drive or operate machinery have been identified.

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.

PHARMACOLOGICAL PROPERTIES:

PHARMACOKINETICS:

After topical application of Mcian 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.

PHARMACODYNAMICS:

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.

PACKAGING:

5 gm laminated tube is packed in a printed carton along with pack insert.

STORAGE CONDITION:

Store in a dry place below 30°C. Protect from light. Keep out of reach of children.

SHELF LIFE:

24 Months

MANUFACTURED BY:

CIAN HEALTH CARE PVT. LTD.

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