1. Name of the medicinal Product

Mupirocin Ointment USP 2.0%w/w

Dermocin Ointment 2.0% w/w

2. Qualitative and Quantitative Composition

Qualitative declaration

Mupirocin USP

Quantitative declaration

For full list of Excipients, see section 6.1.

3. Pharmaceutical Form

Topical ointment

Distribution Category: POM

White to off-white coloured ointment.

4. Clinical Particulars

4.1 Therapeutic Indications

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

4.2 Posology and Method of Administration

Adults (including elderly) and children: Mupirocin Ointment USP 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.

Administration: Topical.

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.

4.3 Contraindications

Mupirocin Ointment USP should not be given to patients with a history of hypersensitivity to any of its constituents.

This Mupirocin Ointment USP formulation is not suitable for ophthalmic or intranasal use.

4.4 Special Warnings and Special Precautions for Use

Should a possible sensitisation reaction or severe local irritation occur with the use of Mupirocin Ointment USP, 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

Renal impairment: Elderly patients: No restrictions unless the condition being treated could lead to absorption of polyethylene glycol and there is evidence of moderate or severe renal impairment.

Mupirocin Ointment USP 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.

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 USP 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.

Pregnancy

Reproduction studies on Mupirocin Ointment in animals have revealed no evidence of harm to the foetus. As there is no clinical experience on its use during pregnancy, Mupirocin Ointment USP 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 Mupirocin Ointment USP in milk. If a cracked nipple is to be treated, it should be thoroughly washed prior to breast feeding.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

Reproduction studies on Mupirocin Ointment in animals have revealed no evidence of harm to the foetus. As there is no clinical experience on its use during pregnancy, Mupirocin Ointment USP 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 Mupirocin Ointment USP in milk. If a cracked nipple is to be treated, it should be thoroughly washed prior to breast feeding.

4.7 Effects on ability to Drive and use Machines

Not known.

4.8 Undesirable Effects

Immune system disorders:

Very rare: Systemic allergic reactions have been reported with Mupirocin Ointment USP.

Skin and subcutaneous tissue disorders:

Common: Burning localized to the area of application.

Uncommon: Itching, erythema, stinging and dryness localized to the area of application.

Uncommon: Cutaneous sensitisation reactions to mupirocin or the ointment base.

4.9 Overdose

The toxicity of Mupirocin Ointment USP is very low. In the event of accidental ingestion of the cream 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.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Pharmacotherapeutic Group: Topical Antibacterial

ATC Code: D06AX09

Mupirocin potently inhibits bacterial protein and RNA synthesis by inhibition of isoleucyl-transfer RNA synthetase.

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.

5.3 Preclinical Safety Data

Pre-clinical effects were seen only at exposures which are extremely unlikely to cause concern for humans under normal conditions of use. Mutagenicity studies revealed no risks to man.

6. Pharmaceutical Particulars

6.1 List of Excipients

Macrogols-400 (Polyethylene glycol 400)

Macrogols-4000 (Polyethylene glycol 4000)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light. Do not freeze.

6.5 Nature and Contents of Container

White to off-white coloured ointment filled in 15 gm of aluminium collapsible tube. Such 1 tube is packed in a printed carton with a packing insert.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses

7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
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Fax: +91-79-41078062
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GENERICS AND SPECIALITIES LIMITED,
9 Dave Anazodo Street, Ajao Estate,
Isolo, Lagos 08033344839
cyril@gslnigeria.com

8. Marketing Authorization Number

To be included after obtaining first registration

9. Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

10. Date of Revision of the Text

March, 2023

11. Dosimetry (If Applicable)

Not Applicable

12. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable