SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **Rociderm Ointment**
1.2 Generic Name : **Mipirocin Ointment BP 2%**
1.3 Strength : **2% w/w**
1.4 Pharmaceutical Form: **Ointment**

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Mupirocin	BP	2% w//w
Ointment Base		q.s.

3. PHARMACEUTICAL FORM

Topical Ointment
White or almost white translucent ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Rociderm (Mupirocin) is indicated for the treatment bacterial skin infections, particularly those caused by Gram-positive organisms (except pseudomonal infection).

4.2 Posology and method of administration

Child : Apply up to 3 times a day for up to 10 days
Adult : Apply up to 3 times a day for up to 10 days
Mupirocin is not recommended for use in children under 1 year.

4.3 Contraindications

Mupirocin Ointment should be contraindicated in patients who have demonstrated hypersensitivity to Mupirocin or any components of the formulations.

4.4 Special warnings and special precautions for use

If a reaction suggesting sensitivity or chemical irritation should occur with the use of Mupirocin Ointment, treatment should be discontinued, the product should be wiped off and appropriate alternative therapy for the infection instituted.

Mupirocin is not suitable for ophthalmic use, intranasal use or application to other mucosal surfaces. Avoid contact with eyes. If contaminated, the eyes should be thoroughly irrigated with water until the residues have been removed. Mupirocin Ointment not suitable for application to the site of cannulation or for use in conjunction with cannulae.

Renal impairment: Caution should be taken when Mupirocin Ointment used in moderate or severe renal impairment as it can be absorbed from open wounds and damaged skin and then excreted by kidney.

4.5 Interaction with other FPPs and Other forms of Interaction

No drug interactions have been identified with Mupirocin. However it should not be combined with other topical preparations as there is a risk of dilution, resulting in a reduction in the antibacterial activity and potential loss of stability of the Mupirocin.

4.6 Pregnancy and lactation

Topical use of Mupirocin Ointment should be avoided during pregnancy and lactation. It should be avoided on the nipple.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effects

Mupirocin Ointment may show side effects like burning sensation, local reactions, pruritus, rash, urticaria.

4.9 Overdose

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage, 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Mupirocin

Pharmacotherapeutic group: Antibacterial

ATC Code: D06AX09

Mechanism of action:

Mupirocin inhibits bacterial RNA and protein synthesis by binding to bacterial isoleucyl tRNA synthetase, which catalyzes the formation of isoleucyl tRNA from isoleucine and tRNA. This prevents incorporation of isoleucine into protein chains, leading to arrest of protein synthesis.

Resistance to mupirocin develops through the production of a modified target enzyme. Because of its unique mechanism of action, there is no cross-resistance between mupirocin and other antimicrobial agents.

5.2 Pharmacokinetic properties

The *in vitro* antibacterial activity is greatest at acidic pH, which is advantageous in the treatment of cutaneous infections because of the low pH of the skin. Mupirocin is poorly absorbed through intact human skin; less than 0.24% of a 0.5 g dose being available systemically following the topical application of Mupirocin.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

P.E.G. -400 (Macrogol-400)	BP
P.E.G. -3350	BP

6.2 Incompatibilities

Not sufficient data available

6.3 Shelf life

24 month from the date of manufacturing.

6.4 Special precautions for storage

Do not freeze. Store at a temperature not exceeding 30°C. Keep out of reach of children.

6.5 Nature and contents of container

15 gm in an aluminium lacquered collapsible tube in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

06845/07308/NMR/2019

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Nov 28, 2021

10. DATE OF REVISION OF THE TEXT
