APPROVED PROFESSIONAL INFORMATION FOR DERMOBAN OINTMENT

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

DERMOBAN OINTMENT (20 mg, ointment)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains 20 mg of mupirocin (2 % *w/w* mupirocin).

For the full list of excipients, see **section 6.1**.

3. PHARMACEUTICAL FORM

Ointments.

White coloured ointment, free of foreign substances

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DERMOBAN OINTMENT is indicated for the topical treatment of primary and secondary bacterial skin infections caused by *Staphylococcus aureus* and other susceptible organisms.

Primary skin infections:

Impetigo, folliculitis, furunculosis and ecthyma.

Secondary infections:

Infected dermatoses e.g., infected eczema. Infected traumatic lesions e.g., abrasions, insect bites, minor (not requiring hospitalisation) wounds and burns.

Prophylaxis:

DERMOBAN OINTMENT may be used to avoid bacterial contamination of small wounds, incisions and other clean lesions, and to prevent infection of abrasions and small cuts and wounds.

4.2 Posology and method of administration

For external use only (see **section 4.4**)

Posology

Adults and children older than 2 months:

DERMOBAN is applied 2 - 3 times a day for up to 10 days, depending on the response.

Hepatic impairment:

As above

Renal impairment:

See **section 4.4.**

Paediatric population

The safety and efficacy of DERMOBAN OINTMENT in babies under 2 months have not yet been established.

Method of administration

Before applying, wash affected areas and dry thoroughly.

A small quantity of DERMOBAN OINTMENT should be applied to cover the affected area.

The treated area(s) may be covered with a gauze dressing if desired.

Complete the full course of treatment.

See **section 6.3** for the product shelf-life after opening.

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 in the ointment.

4.3 Contraindications

- Patients with known hypersensitivity to mupirocin or to any of the excipients used in the formulation of DERMOBAN OINTMENT (see **section 6.1**)
- DERMOBAN OINTMENT is not indicated for the treatment of skin lesions infected with *Pseudomonas aeruginosa*.

4.4 Special warnings and precautions for use

DERMOBAN OINTMENT is not suitable for:

• intranasal use.

• use in conjunction with cannulae.

• at the site of central venous cannulation.

• ophthalmic use.

Avoid contact with the eyes. If accidental contact occurs, the eyes should be thoroughly washed with water until all traces of the ointment have been removed.

Treatment with DERMOBAN OINTMENT should be discontinued in the event of a sensitisation reaction or severe local irritation occurring. DERMOBAN OINTMENT should be rinsed off and alternative therapy for the infection should be prescribed.

Irregular or prolonged use is not recommended as this may result in overgrowth of non-susceptible organisms.

Pseudomembranous colitis has been associated with antibiotic use and can vary in severity from mild to life-threatening. It is therefore important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic treatment. While the risk is lower with topically applied mupirocin, any instance of prolonged or severe diarrhoea, or abdominal cramps, should prompt immediate discontinuation of the treatment and further investigation for the patient.

Renal impairment:

When DERMOBAN OINTMENT is applied to extensive open wounds, damaged skin or burns, the possibility of absorption of polyethylene glycol, resulting in serious renal toxicity, should be considered.

Caution is advised in patients with moderate to severe renal impairment.

4.5 Interaction with other medicines and other forms of interaction

Do not mix with other preparations.

Mixing may result in a decrease in antibacterial activity and a loss of stability of DERMOBAN OINTMENT.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established.

Breastfeeding

It is not known whether DERMOBAN OINTMENT is excreted into breastmilk.

Fertility

There are no data on the effects of mupirocin on human fertility.

4.7 Effects on ability to drive and use machines

DERMOBAN OINTMENT has no or negligible influence on the ability to drive or operate machinery

4.8 Undesirable effects

Tabulated summary of adverse reactions

The following adverse reactions have been classified according to the following categories, frequent, less frequent and frequency unknown.

MedDRA system organ Class	**Frequency**	**Side effects**
Immune system disorders	Less frequent	Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema.
Skin and subcutaneous tissue disorders	Frequent	Burning localised to the area of application
	Less frequent	Itching, erythema, stinging and dryness localised to the area of application, cutaneous sensitation reactions to mupirocin or the ointment base.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. Adverse reactions can also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za.

4.9 Overdose

Symptoms

There is currently limited experience with overdosage of mupirocin.

Management

The toxicity of mupirocin is very low. In the event of accidental ingestion of the ointment, symptomatic treatment should be provided.

In the case of erroneous oral ingestion of large quantities of the ointment, renal function should be closely monitored in patients with renal insufficiency due to the possible side effects of polyethylene glycol.

There is no specific treatment for an overdose of mupirocin. In the event of an 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 20.1.6 Topical Antibiotics

Pharmacotherapeutic group: Antibiotics and chemotherapeutics for topical use

ATC code: D06AX09

- Mechanism of action

Mupirocin is an antibiotic produced by *Pseudomonas fluorescens* that inhibits bacterial protein synthesis by binding to bacterial isoleucyl transfer-RNA synthetase.

It is primarily bacteriostatic at minimum inhibitory concentrations and bactericidal in the higher concentrations achieved by topical application to the skin.

- Resistance

Mupirocin shows little risk of selection of resistant bacteria if used as prescribed, but resistance has emerged, particularly during inappropriate long-term use.

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

Commonly susceptible species:

Streptococcus spp. (β-haemolytic, other than *S. pyogenes*)

Species for which acquired resistance may be a problem:

Staphylococcus spp., coagulase negative

Inherently resistant organisms:

Corynebacterium spp. & *Micrococcus* spp.

5.2 Pharmacokinetic properties

- **Absorption**

Absorption of mupirocin through intact human skin is poor (less than 0,24 %). Mupirocin is however metabolised to the microbiologically inactive metabolite monic acid and rapidly excreted after absorption, when absorbed through broken or diseased skin or after systemic administration.

- **Excretion**

After metabolism to its inactive metabolite monic acid, mupirocin is rapidly eliminated from the body, excreted mainly (90 %) by the kidneys.

Elderly

No restrictions unless there is evidence of moderate or severe renal impairment (see **section 4.4**).

5.3 Preclinical safety data

Exemption requested from inclusion of this section as this is a generic product.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 400

Polyethylene glycol 3350

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 24 months.

Period of use after first opening: 6 months.

6.4 Special precautions for storage

Store at or below 25 °C. Do not refrigerate or freeze.

Replace cap after use.

For storage conditions after first opening of DERMOBAN OINTMENT, see **section 6.3**.

6.5 Nature and contents of container

DERMOBAN OINTMENT is packed in aluminium tubes internally coated with gold epoxy-phenolic lacquer, externally coated with white enamel and closed with white HDPE caps.

Pack sizes:

15 g & 30 g.

One tube is packed into an outer carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Unicorn Pharmaceuticals (Pty) Ltd

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8. REGISTRATION NUMBER

44/20.1.6/0972

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Registration date: 20 April 2015

10. DATE OF REVISION OF THE TEXT

13 February 2025