PROFESSIONAL INFORMATION FOR DERMOBAN OINTMENT

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM:

DERMOBAN OINTMENT

COMPOSITION:

Each gram of **DERMOBAN OINTMENT** contains 20 mg of mupirocin.

Excipients: macrogol and polyethylene glycol.

PHARMACOLOGICAL CLASSIFICATION:

A 20.1.6 Topical Antibiotics

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties

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.

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

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.

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.

CONTRAINDICATIONS:

- Hypersensitivity to mupirocin or any of the ingredients of **DERMOBAN OINTMENT**.
- Treatment of skin lesions infected with *Pseudomonas aeruginosa.*

WARNINGS and SPECIAL PRECAUTIONS:

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 eyes. If accidental contact occurs, wash the eyes thoroughly with water until all traces of the ointment have been removed.

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.

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.

Effects on ability to drive and use machines

DERMOBAN OINTMENT will most likely not affect the patients' ability to drive or operate machinery.

INTERACTIONS:

Do not mix with other preparations. Mixing may result in a decrease in antibacterial activity and a loss of stability of **DERMOBAN OINTMENT**.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children older than 2 months:

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

Instructions for use:

Before applying, wash affected areas and dry thoroughly.

Apply a small quantity of **DERMOBAN OINTMENT** to cover the affected area.

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

Complete the full course of treatment.

Renal impairment:

See **WARNINGS and SPECIAL PRECAUTIONS.**

SIDE EFFECTS:

Infections and Infestations

Less frequent: Secondary wound infection

Nervous system disorders

Less frequent: Dizziness

Immune system disorders

Less frequent: Hypersensitivity reactions

Gastrointestinal disorders

Less frequent: Nausea, abdominal pain, ulcerative stomatitis.

Skin and subcutaneous tissue disorders

Less frequent: Dry skin, skin burning, itching, pain, rash, redness, stinging or swelling, cutaneous sensitisation reactions to mupirocin or the ointment base.

General disorders

Less frequent: Headache

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See **SIDE-EFFECTS AND SPECIAL PRECAUTIONS**.

Treatment is symptomatic and supportive.

IDENTIFICATION:

White colour ointment, free of foreign substances.

PRESENTATION:

15 g or 30 g aluminium tubes internally coated with gold epoxy-phenolic lacquer, externally coated with white enamel and closed with white HDPE caps.

STORAGE INSTRUCTIONS:

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

Replace cap after use.

DERMOBAN OINTMENT can be used for up to 6 months after first opening the tube.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

44/20.1.6/0972

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Unicorn Pharmaceuticals (Pty) Ltd.

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