SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE
SUPIROBAN CREAM (Cream)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
SUPIROBAN CREAM: Each gram of cream contains 21.5 mg of mupirocin calcium (equivalent to 20.0 mg mupirocin free acid) in an oil and water-based emulsion.
Contains preservatives: Benzyl alcohol 1.0 % w/w. For full list of excipients, *see section 6.1.*

3. PHARMACEUTICAL FORM
Cream.
A white soft homogeneous cream.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
SUPIROBAN CREAM 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: Mupirocin 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
Posology
Adults, children, elderly:
2-3 times a day for up to 10 days, depending on the response.
Hepatic impairment: As above.
Renal Impairment: As above.

Method of administration:
SUPIROBAN CREAM is for topical use only.
A small quantity of **SUPIROBAN CREAM** should be applied to cover the affected area.
The treated area may be covered by a dressing.
Any product remaining at the end of treatment should be discarded.
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 cream.

4.3 Contraindications
- **SUPIROBAN CREAM** is contraindicated in patients with a known hypersensitivity to mupirocin calcium or to any of the excipients in the **SUPIROBAN CREAM** (*see section 6.1*)
- **SUPIROBAN CREAM** is not indicated for the treatment of skin lesions infected with Pseudomonas aeruginosa.

4.4 Special warnings and precautions for use
This mupirocin cream formulation is not suitable for:
- ophthalmic use
- intranasal use
- use in conjunction with cannulae
- at the site of central venous cannulation.

Avoid contact with eyes. If contaminated, the eyes should be thoroughly irrigated with water until the cream residues have been removed.
In the event of a sensitisation or severe local irritation from **SUPIROBAN CREAM,** usage should be discontinued, the product should be washed off and appropriate therapy instituted.
Prolonged use of mupirocin cream may result in overgrowth of non-susceptible microorganisms.

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.

SUPIROBAN CREAM formulation is not suitable for ophthalmic or intranasal use.
SUPIROBAN CREAM contains benzyl alcohol which may cause mild local irritation.

4.5 Interaction with other medicines and other forms of interaction
No medicine interactions have been identified.

4.6 Fertility, pregnancy and lactation
The safety in pregnancy and lactation has not been established.
Pregnancy
Reproduction studies on mupirocin in animals have revealed no evidence of harm to the foetus. As there is no clinical experience on its use during pregnancy, **SUPIROBAN CREAM** should not be used in pregnancy.
Breast-feeding
There is no information on the excretion of mupirocin 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.

4.7 Effects on ability to drive and use machines
No adverse effects on the ability to drive or operate machinery have been identified.

4.8 Undesirable effects

MedDRA SOC	Frequency	Undesirable effect
Immune system disorders	Less frequent	Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema
Skin and subcutaneous tissue disorders	Frequent	Application site hypersensitivity reactions including urticaria, pruritus, erythema, burning sensation, contact dermatitis, rash
	Frequency unknown	Skin dryness

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 **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose
Symptoms:
There is currently limited experience with overdosage of **SUPIROBAN CREAM.**
Management:
There is no specific treatment for an overdose of **SUPIROBAN CREAM.** In the event of overdose, the patient should be treated supportively with appropriate monitoring as necessary.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
A 20.1.6 Topical Antibiotics
Dermatologicals ATC code: D06AX, Antibiotics and chemotherapeutics for dermatological use
Mupirocin is an antibiotic produced through fermentation by Pseudomonas fluorescens. Mupirocin inhibits isoleucyl transfer-RNA synthetase, thereby arresting bacterial protein synthesis. Mupirocin shows little risk of selection of resistant bacteria if used as prescribed. Mupirocin has bacteriostatic properties at minimum inhibitory concentrations and bactericidal properties at the higher concentrations reached when applied locally.

5.2 Pharmacokinetic properties:
Absorption
Systemic absorption of mupirocin through intact human skin is low although it may occur through broken/ diseased skin. However, clinical trials have shown that when given systemically, it is metabolised to the microbiologically inactive metabolite monic acid and rapidly excreted.
Elimination:
Mupirocin is rapidly eliminated from the body by metabolism to its inactive metabolite monic acid which is rapidly excreted by the kidney.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Benzyl alcohol, glycerol monostearate 40-55, mineral oil, phenoxyethanol, polyoxyl 20 cetostearyl ether, purified water, xanthan gum.

6.2 Incompatibilities
Not applicable

6.3 Shelf life
18 months

6.4 Special precautions for storage
Store at or below 25 °C. Do not refrigerate.

6.5 Nature and contents of container
1. A filled & crimped 30 g Aluminium tube with cap, packed in a carton along with a leaflet
2. A filled & crimped 15 g Aluminium tube with cap, packed in a carton along with a leaflet
3. 42.5 g of drug product packed in a white Opaque Airless jar and snapfit closed with over capped Pump

6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Glenmark Pharmaceuticals South Africa (Pty) Ltd
34 Monte Carlo Crescent,
Block A, First floor, Kyalami Park,
Midrand,1684

8. REGISTRATION NUMBER(S)
49/20.1.6/0587

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
26 July 2022

10. DATE OF REVISION OF TEXT