PROFESSIONAL INFORMATION

SCHEDULING STATUS **S2**

1 NAME OF THE MEDICINE

PIBAN®, ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Sugar free.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

PIBAN is a white to off-white homogeneous ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

PIBAN 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:

PIBAN 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, children, elderly

PIBAN is applied two to three times daily for up to 10 days, depending on the response.

Hepatic impairment

As above.

Renal impairment

See section 4.4.

Method of administration

A small quantity of PIBAN 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.

See section 6.3 for 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

- Hypersensitivity to mupirocin or to any of the excipients of PIBAN listed in section 6.1.

- PIBAN is not indicated for the treatment of skin lesions infected with *Pseudomonas aeruginosa.*

4.4 Special warnings and precautions for use

PIBAN is not suitable for:

- ophthalmic use
- intranasal use
- use in conjunction with a cannula
- at the site of central venous cannulation.

Avoid contact with the eyes. If contaminated, the eyes should be thoroughly irrigated with water until all ointment residues have been removed.

In the event of a sensitisation reaction or severe local irritation occurring with the use of PIBAN, treatment should be discontinued, the product should be rinsed off and appropriate alternative therapy for the infection should be instituted.

Prolonged or irregular use of PIBAN may result in overgrowth of non-susceptible strains of *S. aureus* and other organisms.

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, including PIBAN. Although this is less likely to occur with topically applied mupirocin as in PIBAN, if prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately, and the patient investigated further.

Special patient groups

Renal impairment

No restrictions, unless the condition being treated could lead to absorption of polyethylene glycol and there is evidence of moderate to severe renal impairment.

Polyethylene glycol can be absorbed from open wounds, burns and damaged skin and is excreted by the kidneys. PIBAN ointment 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. The excretion of polyethylene glycol may be impaired and could lead to nephrotoxicity and severe metabolic disturbances.

4.5 Interaction with other medicines and other forms of interaction

No interactions have been reported.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established.

Lactation

This in no information on the excretion of PIBAN in milk.

Fertility

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

4.7 Effects on ability to drive and use machines

No adverse effects on the ability to drive or to operate machines have been reported.

4.8 Undesirable effects

Tabulated summary of adverse reactions

Immune system disorders	
Less frequent:	Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema (see section 4.4).
Infections and infestations	
Frequency not known:	Superinfection with non-susceptible strains of *S. aureus* and other organisms, pseudomembranous colitis.
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 of PIBAN, (see section 4.4).

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. Healthcare 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

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

Treatment

There is no specific treatment for an overdose of mupirocin as in PIBAN. In the event of overdose, the patient should be treated supportively with appropriate monitoring, as necessary. Further management should be as clinically indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A. 20.1.6 Topical antibiotics

Pharmacotherapeutic group: Antibiotics and chemotherapeutics for dermatological use. ATC code: D06AX09

Mupirocin is an antibiotic, produced through fermentation of *Pseudomonas fluorescens.* It inhibits bacterial protein synthesis by binding to the bacterial isoleucyl t-RNA synthetase.

Mupirocin has bacteriostatic properties at minimum inhibitory concentrations and bactericidal properties at the higher concentrations reached when applied locally.

Resistance

Mupirocin shows little risk of selection of resistant bacteria if used as prescribed.

Low-level resistance in staphylococci is thought to result from point mutations within the usual staphylococcal chromosomal gene (ileS) for the target isoleucyl t-RNA synthetase enzyme. High-level resistance in staphylococci has been shown to be due to a distinct, plasmid encoded isoleucyl t-RNA 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.

Species for which acquired resistance may be a problem

Staphylococcus spp., coagulase negative

Inherently resistant organisms

Corynebacterium spp. and *Micrococcus* spp.

5.2 Pharmacokinetic properties

Absorption

Mupirocin is poorly absorbed (less than 0,24 %) through intact human skin. However, if mupirocin is absorbed (e.g. through broken/diseased skin) or if it is 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 excreted mainly by the kidney (90 %).

Elderly patients

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 400 (polyoxyethylene glycol)

Macrogol 3350 (polyoxyethylene glycol)

6.2 Incompatibilities

None stated.

6.3 Shelf life

Unopened PIBAN: 18 months

Period of use after first opening: 15 days after first opening.

6.4 Special precautions for storage

Store at room temperature, at or below 25 °C. Keep tightly closed. Do not refrigerate.

For storage conditions after first opening of PIBAN, see section 6.3.

6.5 Nature and contents of container

White aluminium tube with an epoxy-phenolic internal lacquer, operculated with an aluminium lid, closed at the upper side by a white polyethylene screw cap and at the bottom side by folds.

The nominal content of the tube is 15 g.

The tube is packed in a cardboard box, together with a leaflet.

6.6 Special precautions for disposal and other handling

Any product remaining at the end of treatment should be discarded.

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

Wash your hands after application.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Macleods Pharmaceuticals SA (Pty) Ltd

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Bassonia Estate Office Park (East)

1 Cussonia Drive

Bassonia Rock Ext 12

Alberton, South Africa

8. REGISTRATION NUMBER

Piban: 52/20.1.6/0255

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04.08.2022

Date of latest renewal: *Pending.*

10. DATE OF REVISION OF THE TEXT

18 October 2023