1.3.1.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

BANOGON OINTMENT 2 % *m/m.*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of BANOGON OINTMENT contains 20 mg mupirocin (2% *m/m* mupirocin)

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment

BANOGON OINTMENT is a white, translucent water miscible ointment.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

BANOGON 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:

BANOGON 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

Posology

Adults:

Apply BANOGON OINTMENT two to three times a day for up to 10 days, depending on the response.

The duration of treatment should not exceed 10 days.

For external use only. Keep out of the eyes. Dilution not recommended. Not for long term use. (See section 4.4).

Special populations

Elderly

As above. No special dosing requirements for the elderly.

Renal impairment:

No dosage adjustment is necessary (see section 4.4).

Hepatic impairment:

As above

Paediatric population

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

Children older than 2 months:

Apply BANOGON OINTMENT two to three times a day for up to 10 days, depending on the response.

The duration of treatment should not exceed 10 days.

For external use only. Keep out of the eyes. Dilution not recommended. Not for long term use. (See section 4.4).

Method of administration

Before applying, wash affected areas and dry thoroughly.

For external use only.

- A small quantity of BANOGON OINTMENT should be applied to cover the affected area.
- The treated area may be covered by a gauze dressing if desired.
- Any product remaining at the end of treatment should be discarded.
- Do not dilute (mix) with other preparations (see section 4.5) 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.

- Not for long-term use (see section 4.4.)

4.3. Contraindications

BANOGON OINTMENT is contraindicated in:

- Patients with known hypersensitivity to mupirocin or to any of the excipients of BANOGON OINTMENT (see section 6.1)
- the treatment of skin lesions infected with *Pseudomonas aeruginosa.*

4.4. Special warnings and precautions for use

The BANOGON OINTMENT formulation 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 contaminated, the eyes should be thoroughly irrigated with water until the ointment residues have been removed.

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

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

BANOGON OINTMENT should be used with caution in patients with extensive burns or wounds because of the possibility of polyethylene/macrogol toxicity (see 6.1).

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

Care is required in patients with moderate to severe renal impairment. Polyethylene glycol can be absorbed from open wounds, burns and damaged skin and is excreted by the kidneys. BANOGON 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

Do not mix with other preparations as there is a risk of dilution, resulting in reduction in the antibacterial activity and potential loss of stability of the mupirocin in the ointment.

4.6. Fertility, pregnancy and lactation

Pregnancy

The safety of BANOGON OINTMENT in pregnancy has not been established.

Breastfeeding

The safety of BANOGON OINTMENT in breastfeeding has not been established. It is not known whether BANOGON OINTMENT is excreted into breastmilk.

Fertility

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

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

a) Tabulated list of adverse reactions

System organ class	**Frequent**	**Less frequent**	**Frequency unknown**
Immune system disorders		Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema.	
Skin and subcutaneous tissue disorders	Burning localised to the area of application	Itching, erythema, stinging and dryness localised to the area of application, cutaneous sensitisation	

		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. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9. Overdose

Symptoms

See section 4.8.

Treatment

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

Category and Class: A. 20.1.6 Topical Antibiotics

Pharmacotherapeutic group: 20.3 Antibiotics and chemotherapeutics for dermatological use

ATC code: D06AX09

Mechanism of action

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

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

Mupirocin has bacteriostatic properties at minimum inhibitory concentrations and

bactericidal properties at the higher concentrations reached when applied locally.

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

Mupirocin is poorly absorbed (less than 0,24 %) through intact human skin. However, if it is absorbed through broken/diseased skin, 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 %).

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

- polyethylene glycol-3350 and polyethylene glycol-400

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store at or below 25 °C.

Keep in original packaging until required for use.

6.5. Nature and contents of container

BANOGON OINTMENT is packed in a collapsible 14 g, 15 g and 50 g aluminium tube with a fitted white, plastic cap.

Each tube is placed in a carton together with a leaflet.

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

0800 122 912

8. REGISTRATION NUMBER

43/20.1.6/1139

9. DATE OF FIRST AUTHORISATION

29 July 2016

10. DATE OF REVISION OF TEXT

21 August 2025

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.

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