1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

BANOGON OINTMENT 2 % *m/m* ointment

Mupirocin

Read all of this leaflet carefully because it contains important information for you

BANOGON OINTMENT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use BANOGON OINTMENT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BANOGON OINTMENT with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What BANOGON OINTMENT is and what it is used for
2. What you need to know before you use BANOGON OINTMENT
3. How to use BANOGON OINTMENT
4. Possible side effects
5. How to store BANOGON OINTMENT
6. Contents of the pack and other information

1. What BANOGON OINTMENT is and what it is used for

BANOGON OINTMENT belongs to a group of medicines called topical antibiotics.

BANOGON OINTMENT is an antibiotic ointment used to treat bacterial skin infections such as infected eczema, infected grazes, insect bites, minor wounds and burns.

It may also be used to prevent bacterial infection of small wounds, cuts and grazes

2. What you need to know before you use BANOGON OINTMENT

Do not use BANOGON OINTMENT if:

- you are allergic to mupirocin or to any of the other ingredients in BANOGON OINTMENT (listed in section 6).
- you have a wound infected with *Pseudomonas aeruginosa* (your doctor will tell you).

Warnings and precautions

Take special care with BANOGON OINTMENT:

Tell your doctor or healthcare provider before using BANOGON OINTMENT if:

- You experience skin irritation on the area where you have applied BANOGON OINTMENT; the ointment should be rinsed off and your doctor will prescribe another type of treatment.
- You suffer from kidney problems, as BANOGON OINTMENT contains polyethylene glycol which in large quantities can cause kidney damage. You must avoid applying BANOGON OINTMENT to large areas of broken or damaged skin, especially if you have kidney problems.
- You have extensive burns or wounds because of the possibility of polyethylene/macrogol toxicity (see Contents of the pack and other information).

BANOGON OINTMENT should not be used:

- In the eyes. If contaminated, the eyes should be thoroughly irrigated with water until the

ointment residues have been removed.

- In the nose.
- In conjunction (together) with cannulae (tube that can be inserted into the body).
- At the site of central venous cannulation (the place where a tube is inserted into your vein).

If you develop prolonged or severe diarrhoea or abdominal cramps during or after treatment with BANOGON OINTMENT, please speak to your doctor. You may have to stop treatment with BANOGON OINTMENT because this could be a potentially serious infection of the colon.

BANOGON OINTMENT should not be used for longer than 10 days. Prolonged or irregular use may result in overgrowth of the organisms.

Children and adolescents

BANOGON OINTMENT may be used in children older than 2 months and adolescents.

Other medicines and BANOGON OINTMENT

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Do not mix BANOGON OINTMENT with other medicines as this may result in BANOGON OINTMENT becoming weaker and not being as effective as it should be.

Pregnancy, breastfeeding and fertility

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

Always tell your healthcare provider if you are using any other medicine. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using BANOGON OINTMENT.

Driving and using machines

BANOGON OINTMENT is not expected to influence your ability to drive or operate machinery. It is not always possible to predict to what extent BANOGON OINTMENT may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which BANOGON OINTMENT affects you (see Possible Side Effects).

3. How to use BANOGON OINTMENT

Do not share medicines prescribed for you with any other person.

Always use BANOGON OINTMENT exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The safety of BANOGON OINTMENT in babies under 2 months has not yet been established (see Warnings and precautions).

Before applying, wash affected areas and dry thoroughly. The usual dose of BANOGON OINTMENT is:

Apply a small amount of BANOGON OINTMENT, just sufficient to cover the affected area, two to three times a day for up to 10 days, depending on the response.

You may like to cover the area with gauze dressing.

Discard any ointment remaining at the end of treatment.

Do not mix BANOGON OINTMENT with other preparations, because they may dilute BANOGON OINTMENT, making it less effective (see Other medicines and BANOGON OINTMENT).

Do not use BANOGON OINTMENT long-term.

For external use only. Keep out of the eyes. Dilution not recommended. Not for long term use.

If you use more BANOGON OINTMENT than you should

Carefully wipe off the extra ointment.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose are burning, redness or dryness of the skin or skin irritations. In severe cases, you may have wheezing, swollen face and rashes.

If you forget to use BANOGON OINTMENT

Do not use a double dose to make up for forgotten individual doses.

If you have missed a dose of BANOGON OINTMENT, use the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to use several doses, contact your doctor without delay.

If you stop using BANOGON OINTMENT

If you stop using BANOGON OINTMENT early, not all of the germs (bacteria) causing your skin infection may have been killed. Your infection may come back. Use BANOGON OINTMENT for as long as directed by your healthcare provider. If you have any further questions on the use of BANOGON OINTMENT, ask your doctor, pharmacist or nurse.

4. Possible side effects

BANOGON OINTMENT can have side effects.

Not all side effects reported for BANOGON OINTMENT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using BANOGON OINTMENT, please consult your healthcare provider for advice.

If any of the following happens, stop using BANOGON OINTMENT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to BANOGON OINTMENT. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Burning of the skin where the ointment is applied.

Less frequent side effects:

- skin rash, wheezing (systemic allergic reactions),
- itching, redness, stinging and dryness of the skin where the ointment has been applied, skin reactions to the ointment

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects 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

By reporting side effects, you can help provide more information on the safety of BANOGON OINTMENT.

5. How to store BANOGON OINTMENT

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BANOGON OINTMENT contains

The active substance is 20 mg of mupirocin per 1 g ointment (2 % *m/m*).

The other ingredients are polyethylene glycol-3350 and polyethylene glycol-400.

What BANOGON OINTMENT looks like and contents of the pack

BANOGON OINTMENT is white, translucent water miscible ointment.

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 are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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