

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** **S2****PIBAN[®], ointment****Mupirocin**

- Read all of this leaflet carefully before you start using PIBAN.
- PIBAN is available without a doctor's prescription, for you to treat a mild illness.
Nevertheless, you still need to use PIBAN carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share PIBAN with any other person.
- Ask your 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 PIBAN is and what it is used for
2. What you need to know before you use PIBAN
3. How to use PIBAN
4. Possible side effects
5. How to store PIBAN
6. Contents of the pack and other information

1. What PIBAN is and what it is used for

PIBAN ointment contains the active substance mupirocin. PIBAN is an antibiotic ointment.

- PIBAN is used to treat bacterial skin infections, such as:
 - infected hair follicles which form pimples containing pus ("folliculitis"),
 - an infectious skin infection with blistering and crusting known as "impetigo", or recurring boils ("furunculosis"),
 - infected eczema, abrasions, insect bites, minor wounds and burns,

- to prevent bacterial contamination and infection of small wounds, cuts and abrasions.

This ointment is only for external use on your skin.

2. What you need to know before you use PIBAN

Do not use PIBAN

- if you are hypersensitive (allergic) to mupirocin or any of the other ingredients of PIBAN (listed in section 6);
- have a skin infection caused by *Pseudomonas aeruginosa* (a certain type of bacterium (germ)).

Warnings and precautions

Take special care with PIBAN:

- PIBAN is not suitable for use in your eyes, nose or around intravenous cannula ('drip') sites. Keep the ointment away from your eyes. If the ointment gets into your eyes accidentally, wash them thoroughly with water until all ointment residues have been removed.
- PIBAN can cause severe skin reactions or allergies.

Tell your doctor or healthcare professional:

- if you have any kidney problems;
- if you have large areas of broken skin that are affected. PIBAN may penetrate broken skin and affect your kidneys;
Large quantities of polyethylene glycol can be absorbed from open wounds and damaged skin and are excreted by the kidneys;
- if you develop a watery diarrhoea with stomach cramps. You may have a severe form of inflammation of the inner lining of the colon which needs prompt treatment. See section 4.

If you apply PIBAN for a prolonged period, or use it less often than prescribed, you may develop another infection, caused by types of germs that are not sensitive to mupirocin (contained in PIBAN). You should keep strictly to your healthcare provider's instructions.

Other medicines and PIBAN

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

Pregnancy and breastfeeding

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 taking this medicine.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machines

It is unlikely that PIBAN will affect your ability to drive or operate machinery.

3. How to use PIBAN

PIBAN is for external use only.

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

Always use PIBAN exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

You usually apply PIBAN two (2x) to three (3x) times a day to the affected skin areas.

1. Wash and dry your hands.
2. Apply a small quantity of PIBAN to cover the affected area of your skin.
3. You can cover the treated area with a dressing, unless your doctor has told you to leave it uncovered.
4. Replace the cap on the tube and wash your hands.

5. Do not mix PIBAN with any other external cream or ointment medicines on the infected area of your skin as this may reduce the effectiveness of PIBAN.

It is important that you use the full course of PIBAN. Do not stop treatment early as your symptoms may disappear before the infection is fully cleared.

Your doctor will tell you how long your treatment with PIBAN will last. The bacteria are normally cleared from your skin within 10 days of starting treatment. Do not use for more than 10 days. Throw away any ointment that is left over.

If you have the impression that the effect of PIBAN is too strong or too weak, tell your doctor or pharmacist.

If you use more PIBAN than you should

If you accidentally swallow PIBAN, contact your doctor or pharmacist for advice.

Do not use PIBAN more frequently than you should.

If you forget to use PIBAN

If you forget to use PIBAN, apply it as soon as you remember and apply the next dose at the usual time. Do not apply a double dose to make up for forgotten individual doses.

4. Possible side effects

PIBAN can have side effects.

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

If any of the following happens, stop using PIBAN 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,

- raised and itchy rash,
- collapse.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- infection and inflammation of the large intestine (pseudomembranous colitis), causing diarrhoea, usually with blood and mucous, stomach pain and fever.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Burning where the ointment is applied.

Less frequent side effects

- Itching, redness, stinging and dryness on your skin in the place where PIBAN is applied.
- Allergic rash, itching, redness or soreness of the skin can also occur on other parts of your body.

Frequency not known

- Superinfection of the skin by germs resistant to PIBAN may develop if PIBAN is used for a long time. If this occurs, tell your doctor, pharmacist or nurse.

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 “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of PIBAN.

5. How to store PIBAN

Store all medicines out of reach of children.

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

Do not store in a bathroom.

Do not use after the expiry date stated on the carton and tube.

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 PIBAN contains

- The active substance is mupirocin. Each gram of ointment contains 20 mg mupirocin.
- The other ingredients are macrogol 400 (polyoxyethylene glycol) and macrogol 3350 (polyoxyethylene glycol).

What PIBAN looks like and contents of the pack

PIBAN is a white to off-white, homogeneous ointment.

Available in a 15 g 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.

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

Holder of Certificate of Registration

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This leaflet was last revised in

04 August 2022.

Registration number

Piban: 52/20.1.6/0255.254

Access to the corresponding Professional Information

Please refer to the SAHPRA repository for Professional Information and Patient Information

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