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	85002943 PIL Mupirocine 2 %, Ointment, 15 g - Piban	“Vetprom”AD

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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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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/.

MACLEODS

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Code Reading direction

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S2

PIBAN®, salf
Mupirosien

- Lees die hele inligtingsblad aandagtig deur voordat jy begin om **PIBAN** te gebruik.
- **PIBAN** is beskikbaar sonder voorskrif van 'n dokter, sodat jy 'n ligte siekte kan behandel. Jy sal **PIBAN** nogtans versigtig moet gebruik om die beste resultate daarmee te behaal.
- Hou hierdie inligtingsblad. Dit is moontlik dat jy dit weer sal wil deurlees.
- Moenie **PIBAN** met enige ander persoon deel nie.
- Vra jou apteker indien jy meer inligting of raad benodig.
- Jy moet 'n dokter spreek as jou simptome vererger of nie na 10 dae verbeter nie.

Wat is in hierdie inligtingsblad

1. Wat **PIBAN** is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy **PIBAN** gebruik
3. Hoe om **PIBAN** te gebruik
4. Moontlike newe-effekte
5. Hoe om **PIBAN** te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat PIBAN is en waarvoor dit gebruik word
PIBAN salf bevat die aktiewe bestanddeel mupirosien. **PIBAN** is 'n antibiotiese salf.
- **PIBAN** word gebruik om bakteriële velinfeksies te behandel, soos:
  - geïnfekteerde haarfollikels wat puisies met etter vorm (“follikulitis”),
  - 'n aansteeklike velinfeksie met blaasvorming en korsvorming bekend as "impetigo", of wederkerende pitswere ("furunkulose"),
  - geïnfekteerde ekseem, skaafplekke, insekbyte, geringe wonde en brandplekke,
  - om bakteriële kontaminasie en infeksie van geringe wonde, sny- en skaafplekke te voorkom.

Hierdie salf is slegs vir uitwendige gebruik, op jou vel.

2. Wat jy moet weet voordat jy PIBAN gebruik
Moet nie PIBAN gebruik nie
- indien jy hipersensitief (allergies) is vir mupirosien of enige van die ander bestanddele van **PIBAN** (gelys in afdeling 6);
- indien jy 'n velinfeksie het wat veroorsaak word deur *Pseudomonas aëruginosa* ('n sekere tipe bakterie (kiem)).

Waarskuwings en voorsorgmaatreëls
Wees versigtig met **PIBAN**:
- **PIBAN** is nie geskik vir gebruik in jou oë, neus of naby binneaarse naalde (“drup-plekke”) nie. Hou die salf weg van jou oë. Indien die salf per ongeluk in jou oë kom, spoel dit deeglik met water totdat alle oorblyfsels van die salf verwyder is.
- **PIBAN** kan erge velreaksies of allergieë veroorsaak.

Lig jou dokter of gesondheidsorgverskaffer in:
- indien jy enige nierprobleme het;
- indien jy groot areas met stukkende, aangetaste vel het. **PIBAN** kan stukkende vel binnedring en jou niere aantas;
  Groot hoeveelhede poliëtileenglikol kan uit oop wonde en beskadigde vel geabsorbeer word en dit word deur die niere uitgeskei;
- indien jy 'n waterige diarree met maagkrampe ontwikkel. Jy kan 'n ernstige vorm van ontsteking van die binnewand van die dikderm hê wat vinnig behandel moet word. Kyk afdeling 4.

Indien jy **PIBAN** vir 'n langer tydperk of minder gereeld gebruik as wat voorgeskryf is, kan jy 'n ander infeksie kry wat veroorsaak word deur kiemsoorte wat nie sensitief vir mupirosien (bevat in **PIBAN**) is nie. Jy moet streng bly by jou gesondheidsorgverskaffer se aanwysings.

Ander medisyne en PIBAN
Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Swangerskap en borsvoeding
Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy hierdie medisyne gebruik.
Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie.

Bestuur en die gebruik van masjinerie
Dit is onwaarskynlik dat **PIBAN** jou vermoë om te bestuur of masjinerie te hanteer, sal aantas.

3. Hoe om PIBAN te gebruik
PIBAN is slegs vir uitwendige gebruik.
Moenie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.
Gebruik **PIBAN** altyd presies soos jou dokter of apteker jou aangeraai het. Indien jy nie seker is nie, vra jou dokter of apteker.

Gewoonlik wend jy **PIBAN** twee (2x) tot drie (3x) keer per dag aan op die aangetaste velareas.
1. Was en droog jou hande af.
2. Wend 'n klein hoeveelheid **PIBAN** aan om die aangetaste area van jou vel te bedek.
3. Jy kan die behandelde area met 'n verband bedek, tensy jou dokter jou versoek het om dit nie te bedek nie.
4. Plaas die dop terug op die buis en was jou hande.
5. Moenie **PIBAN** met enige ander uitwendige medisinale room of salf op die besmette area van jou vel meng nie, aangesien dit die doeltreffendheid van **PIBAN** kan verminder.

Dit is belangrik dat jy die volle kursus **PIBAN** gebruik. Moenie die behandeling voortydig stop nie, aangesien jou simptome kan verdwyn voordat die infeksie heeltemal opgeklaar is.

Jou dokter sal jou inlig hoe lank jou behandeling met **PIBAN** sal aanhou. Die bakterieë op jou vel sal gewoonlik binne 10 dae na aanvang van behandeling vernietig word. Moenie langer as 10 dae gebruik nie. Gooi enige salf wat oorbly weg.
Indien jy die indruk kry dat die effek van **PIBAN** te sterk of te swak is, lig jou dokter of apteker in.

Indien jy meer PIBAN gebruik as wat jy moes
Indien jy per abuis **PIBAN** insluk, kontak jou dokter of apteker vir raad. Moenie **PIBAN** meer dikwels gebruik as wat jy moet nie.

Indien jy vergeet om PIBAN te gebruik
Indien jy vergeet om **PIBAN** te gebruik, dien dit toe sodra jy onthou en dien dan die volgende dosis op die gewone tyd toe. Moenie 'n dubbeldosis aanwend om op te maak vir 'n vergete individuele dosis nie.

4. Moontlike newe-effekte
PIBAN kan newe-effekte hê.
Nie alle newe-effekte wat vir **PIBAN** aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan of jy enige ongunstige effekte ervaar terwyl jy **PIBAN** gebruik, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, staak die gebruik van PIBAN en lig jou dokter dadelik in daarvan, of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak met sluk of asemhaling,
- opgehewe en jeukerige uitslag,
- ineenstorting.

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie op **PIBAN**. Jy kan dringende mediese aandag of hospitalisering benodig.

Lig jou dokter dadelik in, of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy die volgende waarneem:
- infeksie en inflammasie van die dikderm (pseudomembraneuse kolitis) wat diarree, gewoonlik met bloed en slym, maagpyn en koors veroorsaak.

Hierdie is almal ernstige newe-effekte. Jy kan dringende mediese aandag benodig.
Lig jou dokter in indien jy enige van die volgende waarneem:
Algemene newe-effekte:
- Branderigheid waar die salf aangewend word.

Minder algemene newe-effekte
- Jeukerigheid, rooiheid, branderigheid en droogheid van jou vel op die plek waar **PIBAN** aangewend word.
- Allergiese uitslag, jeukerigheid, rooiheid of seerheid van die vel kan ook op ander dele van jou liggaam voorkom.

Frekwensie onbekend
- Superinfeksie van die vel deur kieme wat weerstand bied teen **PIBAN** kan ontwikkel as **PIBAN** vir 'n lang tyd gebruik word. Indien dit voorkom, lig jou dokter, apteker of verpleegster in.

Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die "**6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn onder SAHPRA se publikasies verskyn: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van **PIBAN** te verskaf.

5. Hoe om PIBAN te bewaar
Bewaar alle medisyne buite bereik van kinders.
Bewaar by of benede 25 °C. Hou die bottel diggeslote. Moenie in die yskas plaas nie.
Moenie in 'n badkamer berg nie.
Moenie na die vervaldatum wat op die kartondosie en flessie verskyn gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting
Wat PIBAN bevat
- Die aktiewe bestanddeel is mupirosien. Elke gram salf bevat 20 mg mupirosien.
- Die ander bestanddele is makrogol 400 (poli-oksiëtileenglikol) en makrogol 3350 (poli-oksiëtileenglikol).

Hoe PIBAN lyk en inhoud van die pakkie
PIBAN is 'n wit tot amperwit, homogene salf.
Beskikbaar in 'n 15 g aluminiumbuis met 'n epoksie-fenoliese binneste lak, voorsien van 'n aluminiumdop, bo toegemaak met 'n wit poliëtileen-skroefdop en onder met voue.
Elke buisie word saam met 'n inligtingsblad in 'n kartonhouer verpak.

Houer van die Registrasiesertifikaat
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Toegang tot die ooreenstemmende Professionele Inligting
Verwys asseblief na die SAHPRA-bewaarplek vir Professionele Inligting en Pasiëntinligtingsblaaie:
https://www.sahpra.org.za/pi-pil-repository/.

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