APPROVED PATIENT INFORMATION LEAFLET FOR DERMOBAN OINTMENT

SCHEDULING STATUS

S2

DERMOBAN OINTMENT (20 mg, ointment)

Mupirocin

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

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

- Keep this leaflet. You may need to read it again.
- Do not share DERMOBAN OINTMENT with any other person.
- Ask your health care 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 DERMOBAN OINTMENT is and what it is used for
2. What you need to know before you use DERMOBAN OINTMENT
3. How to use DERMOBAN OINTMENT
4. Possible side effects
5. How to store DERMOBAN OINTMENT
6. Contents of the pack and other information.

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

DERMOBAN OINTMENT (mupirocin) belongs to a class of medicine known as antibiotics.

DERMOBAN OINTMENT is used to kill certain bacteria which cause skin infections.

DERMOBAN OINTMENT is indicated in the treatment of:

- a contagious skin infection that causes red itchy sores or blisters on the face (impetigo) which may develop into painful deep ulcers (ecthyma), infected hair follicles which has formed pimples containing pus (folliculitis), or boils which may reoccur (furunculosis),
- skin infections caused by infected eczema and other infected injuries such as grazes or scratches caused by insect bites, minor wounds and burns,
- to prevent bacterial skin infections of small wounds or cuts.

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

Do not use DERMOBAN OINTMENT if:

- you are hypersensitive (allergic) to mupirocin or to any of the other ingredients of DERMOBAN OINTMENT (listed in **Section 6**).
- you have a skin infection called *Pseudomonas aeruginosa* (which is a certain type of germ).

Warnings and Precautions

Take special care with DERMOBAN OINTMENT:

- DERMOBAN OINTMENT is not suitable to use in your eyes or nose.
- If DERMOBAN OINTMENT accidentally gets into your eye, wash thoroughly with water until all of the ointment is removed.
- DERMOBAN OINTMENT is not suitable for use with tubes inserted into your body for the delivery or removal of fluid (cannulae).
- If you have a kidney disorder. If DERMOBAN OINTMENT is applied to large open wounds, damaged skin or burns, large amounts of polyethylene glycol may penetrate the broken skin, be absorbed and damage your kidneys.
- If you develop stomach cramps with prolonged or severe watery diarrhoea. Stop using DERMOBAN OINTMENT and contact your doctor or healthcare professional immediately as you may have a severe form of inflammation of the inner lining of the large intestine (pseudomembranous colitis)

- If you experience a severe skin irritation after applying DERMOBAN OINTMENT, rinse off with water and contact your doctor for an alternative treatment.
- Do not use DERMOBAN OINTMENT for long periods of time as you may develop other types of infection on your skin.

Children and adolescents

Do not give DERMOBAN OINTMENT to babies under 2 months of age.

Other medicines and DERMOBAN OINTMENT

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

Mixing of **DERMOBAN OINTMENT** with other ointments or creams may cause **DERMOBAN OINTMENT** to be less effective. It is not recommended to mix **DERMOBAN OINTMENT** with other products.

Pregnancy, breastfeeding and fertility

Safety in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, 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 DERMOBAN OINTMENT.

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

Driving and using machines

DERMOBAN OINTMENT will most likely not affect your ability to drive or operate machinery.

It is not always possible to predict to what extent DERMOBAN OINTMENT may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DERMOBAN OINTMENT affects them.

3. How to use DERMOBAN OINTMENT

DERMOBAN OINTMENT is for external use only.

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

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

- Adults and children older than 2 months: Apply 2 – 3 times a day to the affected area for up to 10 days
- Before applying, wash the affected area and dry thoroughly.
- Apply a small quantity of DERMOBAN OINTMENT to cover the affected area.
- You can cover the treated area with a gauze dressing.
- Continue to apply for the full period of time as prescribed by your doctor or pharmacist, even if the infection seemed to clear up.
- Do not mix DERMOBAN OINTMENT with any other medicine as this may reduce the effectiveness of the DERMOBAN OINTMENT.

Your healthcare provider will tell you how long your treatment with DERMOBAN OINTMENT will last. Do not use for longer than 10 days.

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

If you use more DERMOBAN OINTMENT than you should

Carefully wipe off the extra ointment. Do not use more of DERMOBAN OINTMENT than prescribed or for longer periods than prescribed, it may cause the bacteria to become resistant against DERMOBAN OINTMENT.

If you forget to use DERMOBAN OINTMENT

Apply DERMOBAN OINTMENT as soon as you remember. If it is almost time for your next application, skip the missed application and apply at the usual time. Do not apply a double dose to make up for forgotten individual doses.

If you stop using DERMOBAN OINTMENT

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

4. Possible side effects

DERMOBAN OINTMENT can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, 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 allergic reaction to DERMOBAN OINTMENT. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Burning where the ointment is applied.

Less frequent side effects:

- Redness, itching, stinging and dryness where the ointment is applied.
- Red, itchy bumpy allergic rash or soreness of the skin on the face, hands or body.

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 the SAHPRA website https://www.sahpra.org,za/Publications/Index/8. Side effects can also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za. By reporting side effects, you can help provide more information on the safety of DERMOBAN OINTMENT.

5. How to store DERMOBAN OINTMENT

- Store at or below 25 °C. Do not refrigerate or freeze.
- Replace cap after use.
- DERMOBAN OINTMENT can be used for up to 6 months after first opening the tube.
- For external use only.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DERMOBAN OINTMENT contains

The active substance is mupirocin.

The other ingredients are macrogol and polyethylene glycol

What DERMOBAN OINTMENT looks like and contents of the pack

DERMOBAN OINTMENT: a white coloured ointment, free of foreign substances.

DERMOBAN OINTMENT: Is presented in 15 g or 30 g aluminium tubes internally coated with gold epoxy-phenolic lacquer, externally coated with white enamel and closed with white HDPE caps.

Holder of Certificate of Registration

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