PATIENT INFORMATION LEAFLET

NUBAN OINTMENT

SCHEDULING STATUS:

S2

NUBAN OINTMENT

Mupirocin 2 % *(m/m)*

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

NUBAN OINTMENT is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use NUBAN OINTMENT carefully to get the best results from it.

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

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

NUBAN OINTMENT contains mupirocin, one of a group of medicines called antibiotics.

NUBAN OINTMENT is a topical antibiotic.

It is used to treat skin infections such as:

- infected hair follicles which form pimples containing pus ("folliculitis")

- an infectious skin infection with blistering and crusting known as impetigo
- recurring boils also known as furunculosis
- infected eczema
- infected injuries such as grazes or scratches caused by insect bites, minor wounds and burns.

It is also used to prevent bacterial skin infections of small wounds or cuts.

2. What you need to know before you apply NUBAN OINTMENT

Do not apply NUBAN OINTMENT if:

- you are hypersensitive (allergic) to mupirocin or any of the other ingredients in NUBAN OINTMENT (see section 6)
- you have a skin infection caused by *Pseudomonas aeruginosa*.

Warnings and precautions

Take special care with NUBAN OINTMENT:

- NUBAN OINTMENT is not suitable to use in the eyes or nose
- if NUBAN OINTMENT accidentally gets into the eye, wash thoroughly with water until all of the ointment is removed
- NUBAN 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 you have large areas of broken skin that are affected, NUBAN OINTMENT 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 experience a severe skin irritation after applying NUBAN OINTMENT, rinse off with water and contact your doctor for an alternative treatment.

Do not use NUBAN OINTMENT for long periods of time as you may develop other types of infection on your skin.

Pseudomembranous colitis (swelling or inflammation of the large colon) has been reported with the use of antibiotics.

If you develop severe and prolonged diarrhoea during or after antibiotic use, discontinue treatment immediately and talk to your doctor or pharmacist.

Other medicines and NUBAN OINTMENT

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

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

Pregnancy and breastfeeding

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 NUBAN OINTMENT.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machines

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

3. How to use NUBAN OINTMENT

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

Always use NUBAN 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.

Do not mix NUBAN OINTMENT with any external cream or ointment medicines on the infected area of your skin. This could reduce the effectiveness of the treatment.

Adults, elderly and children (older than 2 months):

- before applying, wash the affected area and dry thoroughly
- apply 2 – 3 times a day for up to 10 days as prescribed by your doctor or pharmacist
- apply a small quantity of NUBAN OINTMENT to cover the affected area
- the treated area may be covered with a gauze dressing.

How long you should use NUBAN OINTMENT for

Continue to apply for the full period of time as prescribed by your doctor or pharmacist, even if the infection seemed to clear up.

Your doctor or pharmacist will tell you how long your treatment with NUBAN OINTMENT will last.

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

If you use more NUBAN OINTMENT than you should

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

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

If you forget to use NUBAN OINTMENT

- apply it 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 NUBAN OINTMENT

If you stop using NUBAN OINTMENT too early, not all the bacteria may have been killed or they may continue to grow. Ask your doctor or pharmacist when to stop using the ointment.

4. Possible side effects

NUBAN OINTMENT can have side effects.

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

If any of the following happens, stop using NUBAN 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
- burning or itching of the skin, rash
- fainting.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- burning feeling of the skin where ointment is applied.

Less frequent side effects:

- secondary wound infection (another infection occurs when treating an infected wound)
- dizziness
- dry skin, redness, stinging or swelling of the skin
- headache.

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 or pharmacist. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by using either of the following links: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/ or https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of NUBAN OINTMENT. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store NUBAN OINTMENT

Store all medicines out of reach of children.

Store at or below 25 ˚C. Do not refrigerate or freeze.

Replace cap after use.

NUBAN OINTMENT can be used for up to 6 months after first opening the tube.

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

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 NUBAN OINTMENT contains

The active substance is mupirocin. Each gram of NUBAN OINTMENT contains mupirocin 20 mg.

The other ingredients are:

- macrogol 400
- polyethylene glycol 3350.

What NUBAN OINTMENT looks like and contents of the pack

NUBAN OINTMENT is white in colour and free from foreign particles.

NUBAN OINTMENT is packed into 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. One tube is packed in an outer carton.

*Not all pack sizes are marketed.

Holder of Certificate of Registration

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