Package Leaflet: Information for the user MUPIROCIN 20 mg/g ointment mupirocin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What MUPIROCIN ointment is and what it is used for

MUPIROCIN 20 mg/g ointment (called 'MUPIROCIN ointment' in this leaflet) contains the active substance called mupirocin.

MUPIROCIN ointment is an antibiotic ointment for external use on your skin only.

It is used in adults, adolescents, children and infants aged 4 weeks and older:

- to treat infections on the skin such as
 - infected hair follicles which form pimples containing pus ('folliculitis'),
 - an infectious skin infection with blistering and crusting ('impetigo') or
 - recurring boils ('furunculosis').
- to kill various bacteria which cause other skin infections including *Staphylococci*, *Streptococci* and *E. coli*. This group includes MRSA (Methicillin Resistant *Staphylococcus aureus*).

2. What you need to know before you use MUPIROCIN ointment

Do not use MUPIROCIN ointment:

- if you are allergic to mupirocin or any of the other ingredients of this medicine (listed in section 6.).
- in your eyes, nose or around intravenous cannula ('drip') sites.

Do not use if the above applies to you. If you are not sure do not use this medicine. Talk to your doctor or pharmacist before using MUPIROCIN ointment.

Warnings and precautions

Talk to your doctor or pharmacist before using MUPIROCIN ointment.

MUPIROCIN ointment can cause severe skin reactions or allergies. See 'Conditions to look out for' in section 4.

Thrush (a yeast infection) may develop if MUPIROCIN ointment is used for a long time. If this occurs, tell your doctor or pharmacist.

Keep the ointment away from your eyes. If the ointment gets into your eyes accidentally, wash them thoroughly with water.

Children

Do not use MUPIROCIN ointment in newborns under 4 weeks of age.

Other medicines and MUPIROCIN ointment

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

If a cracked nipple is being treated, the ointment must be thoroughly washed off prior to breast-feeding.

Driving and using machines

MUPIROCIN ointment has no effects on the ability to drive or use machines.

MUPIROCIN ointment contains polyethylene glycol

Talk to your doctor before using this medicine if you:

- have kidney problems
- have large areas of open wounds or damaged skin to be treated

MUPIROCIN ointment contains butylated hydroxytoluene (E 321) and may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3. How to use MUPIROCIN ointment

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Using this medicine

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

You usually apply MUPIROCIN ointment on your skin 2 to 3 times a day.

- 1. Wash and dry your hands before you open the tube.
- 2. Apply ointment to the infected area of your skin.
- 3. You can cover the treated area with a plaster(s) or suitable dressing(s), unless your doctor has told you to leave it uncovered.
- 4. Replace the cap on the tube and wash your hands.

How long should you use MUPIROCIN ointment for?

Use MUPIROCIN ointment for as long as your doctor has told you. If you are not sure, ask your doctor or pharmacist. 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 use more MUPIROCIN ointment than you should

- If you use more MUPIROCIN ointment than you should, speak to your doctor or pharmacist for advice.
- Remove excessive ointment with a clean wad of cotton wool or gauze swab.
- If you swallow MUPIROCIN ointment, contact your doctor immediately and indicate what and how much you have swallowed.

If you forget to use MUPIROCIN ointment

- If you forget to apply MUPIROCIN ointment, apply it as soon as you remember.
- If your next dose is due within an hour, skip the missed dose.
- Do not use a double dose to make up for a forgotten dose.

If you stop using MUPIROCIN ointment

If you stop using MUPIROCIN 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Conditions to look out for

Severe skin reactions or allergies

These are very rare in people using MUPIROCIN ointment. Signs include:

- raised and itchy rash
- swelling, sometimes of the face or mouth, causing difficulty in breathing
- collapse or loss of consciousness.
 - → Contact a doctor immediately if you get any of these symptoms. Stop using MUPIROCIN ointment.

If you develop a severe skin reaction or an allergy:

- wash off the ointment
- stop using it and
- tell your doctor as soon as possible.

On rare occasions, medicines like MUPIROCIN ointment can cause inflammation of the colon (large intestine), causing diarrhoea, usually with blood and mucus, stomach pain, fever (pseudomembranous colitis).

\rightarrow Tell your doctor as soon as possible if you get any of these symptoms.

The following side effects may happen with this medicine:

Common (may affect up to 1 in 10 people)

• Burning where the ointment is applied.

Uncommon (may affect up to 1 in 100 people)

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

Very rare (may affect up to 1 in 10,000 people)

• Swollen face and/or difficulty breathing. This may be a sign of a serious allergic reaction that could require emergency treatment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MUPIROCIN ointment

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C.

Do not use this medicine after the expiry date which is stated on the tube and on the box after 'EXP:'. The expiry date refers to the last day of that month.

Once opened store tube below 25 °C. After first opening contents can be used up to 10 days.

MUPIROCIN ointment is a homogenous off-white ointment. Do not use MUPIROCIN ointment if it looks different to normal.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What MUPIROCIN ointment contains

- The active substance is mupirocin.
 1 g of ointment contains 20 mg mupirocin.
- The other ingredients are polyethylene glycol 400 and polyethylene glycol 3350 (with butylated hydroxytoluene (E 321)).

What MUPIROCIN ointment looks like and contents of the pack

- MUPIROCIN ointment is a homogenous off-white ointment.
- MUPIROCIN ointment is available in 5 g or 15 g aluminium tubes. Each tube comes in a carton. Cartons may be bundled to receive packs of 2 x 5 g, 3 x 5 g or 2 x 15 g.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

INFECTOPHARM Arzneimittel und Consilium GmbH Von-Humboldt-Str. 1 64646 Heppenheim Germany

Distributor in the United Kingdom:

Esteve Pharmaceuticals Ltd The Courtyard Barns Choke Lane Cookham Dean Maidenhead Berkshire, SL6 6PT

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

GermanyINFECTOPYODERM 20 mg/g SalbeUnited KingdomMUPIROCIN 20 mg/g ointment

This leaflet was last revised in September 2022.