

PACKAGE LEAFLET: INFORMATION FOR THE USER

BETRION

20 mg/g ointment

MUPIROCIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What Betrion ointment is and what it is used for
2. What do you need to know before you use Betrion ointment
3. How to use Betrion ointment
4. Possible side effects
5. How to store Betrion ointment

1. WHAT BETRION OINTMENT IS AND WHAT IT IS USED FOR

Betrion ointment contains a medicine called mupirocin.

Betrion 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 BETRION OINTMENT

Do not use Betrion ointment:

- if you are allergic to mupirocin or any of the other ingredients of this medicine.
- 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 Betrion ointment.

Warnings and precautions

Talk to your doctor or pharmacist before using Betrion ointment.

Betrion ointment can cause severe skin reactions or allergies. See 'Conditions to look out for' in section 4. Thrush (a yeast infection) may develop if Betrion 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 Betrion ointment in newborns under 4 weeks of age.

Other medicines and Betrion ointment

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 taking this medicine.

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

Driving and using machines

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

Betrion 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

3. HOW TO USE BETRION OINTMENT

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Using this medicine

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

You usually apply Betrion 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 Betrion ointment for?

Use Betrion 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.

If your skin condition does not improve within 3 to 5 days, see your doctor.

If you use more Betrion ointment than you should

- If you use more Betrion 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 Betrion ointment, contact your doctor immediately and indicate what and how much you have swallowed.

If you forget to use Betrion ointment

- If you forget to apply Betrion 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 Betrion ointment

If you stop using Betrion 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

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.

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

5. HOW TO STORE BETRION 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.

Do not use Betrion 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.

This leaflet was last revised in April 2014