

Bactroban Ointment

Mupirocin free acid

QUALITATIVE AND QUANTITATIVE COMPOSITION

2% w/w mupirocin free acid in a white, translucent, water soluble, polyethylene glycol base.

PHARMACEUTICAL FORM

Ointment.

CLINICAL PARTICULARS

Indications

Bacterial skin infections, e.g. impetigo, folliculitis and furunculosis.

Dosage and Administration

Adults (including elderly / hepatically impaired) and Children:

Two to three times a day for up to ten days, depending on the response.

Renally impaired

See section *Special warnings and precautions for use*

Method of Administration

For topical administration.

A small quantity of Bactroban ointment should be applied to cover the affected area. The treated area may be covered by a dressing.

Any product remaining at the end of treatment should be discarded.

Do not mix with other preparations as there is a risk of dilution, resulting in a reduction of the antibacterial activity and potential loss of stability of the mupirocin in the ointment.

Contraindications

Hypersensitivity to mupirocin or any of the constituents of the preparations (in List of Excipients).

This Bactroban Ointment formulation is not suitable for ophthalmic or intranasal use.

Special warnings and precautions for use

Should a possible sensitisation reaction or severe local irritation occur with the use of Bactroban Ointment, treatment should be discontinued, the product should be washed off and appropriate therapy instituted.

As with other antibacterial products, prolonged use may result in overgrowth of nonsusceptible organisms.

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. Although this is less likely to occur with topically applied mupirocin, if prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

Renal impairment

Polyethylene glycol can be absorbed from open wounds and damaged skin and is excreted by the kidneys. In common with other polyethylene glycol based ointments, mupirocin ointment should not be used in conditions where absorption of large quantities of polyethylene glycol is possible, especially if there is evidence of moderate or severe renal impairment.

Bactroban ointment is not suitable for:

- ophthalmic use
- intranasal use (in neonates or infants)
- use in conjunction with cannulae and
- at the site of central venous cannulation.

Avoid contact with the eyes. If contaminated, the eyes should be thoroughly irrigated with water until the ointment residues have been removed.

Interaction with other medicinal products and other forms of interaction

No drug interactions have been identified.

Fertility, pregnancy and lactation

Fertility: There are no data on the effects of mupirocin on human fertility. Studies in rats showed no effects on fertility.

Pregnancy: Reproduction studies on Bactroban in animals have revealed no evidence of harm to the foetus. As there is no clinical experience on its use during pregnancy, Bactroban should only be used in pregnancy when the potential benefits outweigh the possible risks of treatment.

Breast-feeding: There is no information on the excretion of Bactroban in milk. If a cracked nipple is to be treated, it should be thoroughly washed prior to breast feeding.

Effects on ability to drive and use machines

No adverse effects on the ability to drive or operate machinery have been identified.

Undesirable effects

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon

($\geq 1/1000$, $< 1/100$), rare ($\geq 1/10,000$, $< 1/1000$), very rare ($< 1/10,000$), including isolated reports.

Common and uncommon adverse reactions were determined from pooled safety data from a clinical trial population of 1573 treated patients encompassing 12 clinical studies. Very rare adverse reactions were primarily determined from post-marketing experience data and therefore refer to reporting rate rather than true frequency.

Immune system disorders:

Very rare: Systemic allergic reactions including anaphylaxis, generalized rash, urticarial and angioedema have been reported with Bactroban Ointment.

Skin and subcutaneous tissue disorders:

Common: Burning localised to the area of application.

Uncommon: Itching, erythema, stinging and dryness localised to the area of application. Cutaneous sensitisation reactions to mupirocin or the ointment base.

Overdose

Symptoms and signs

There is currently limited experience with overdosage of mupirocin.

Treatment

There is no specific treatment for an overdose of mupirocin. In the event of overdose, the patient should be treated supportively with appropriate monitoring as necessary. Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

PHARMACEUTICAL PARTICULARS

List of Excipients

Polyethylene glycol 400, Polyethylene glycol 3350

Incompatibilities

None reported.

Use and Handling

Any product remaining at the end of treatment should be discarded.
Wash your hands after application.

Bactroban is a registered trade mark of the GSK group of companies

© 2017 GSK group of companies. All Rights Reserved

Version number: HK122016 (GDS15/UKSPC20160720)

Package Leaflet: Information for the User

Bactroban Ointment mupirocin free acid

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, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

What Bactroban is and what it is used for

Bactroban 2% Ointment (called ‘Bactroban’ in this leaflet) contains the active substance called mupirocin. Bactroban is an antibiotic ointment.

It is used:

- to treat skin infections on the skin 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”)
- This ointment is for external use on your skin only.

What you need to know before you use Bactroban

Do not use Bactroban:

- if you are allergic (hypersensitive) to mupirocin or any of the other ingredients of this medicine (listed in *Contents of the pack and other information*).

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

Warnings and precautions

- Bactroban can cause severe skin reactions or allergies. See ‘Conditions to look out for’ in *Possible side effects*
 - Bactroban is not suitable for use in your eyes, nose or around intravenous cannula (‘drip’) sites. Thrush (a yeast infection) may develop if Bactroban is used for a long time. If this occurs, tell your doctor, pharmacist or nurse.
- Keep the ointment away from your eyes.
- If the ointment gets into your eyes accidentally, wash them thoroughly with water.

Other medicines and Bactroban

Tell your doctor, nurse 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 or pharmacist 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

It is unlikely that Bactroban will affect your ability to drive or operate machinery.

Bactroban 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

How to use Bactroban

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

Using this medicine

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

You usually apply Bactroban on your skin two to three times a day.

1. Wash and dry your hands.
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 Bactroban for?

Use Bactroban for as long as your doctor has told you. If you are not sure, ask your doctor, nurse 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 swallow any Bactroban

If you swallow any of the ointment, speak to your doctor, nurse or pharmacist for advice.

If you forget to use Bactroban

- If you forget to apply Bactroban, 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 Bactroban

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

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

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 Bactroban 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 Bactroban.

- 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 Bactroban can cause inflammation of the colon (large intestine), causing diarrhoea, usually with blood and mucus, stomach pain, fever (*pseudomembranous colitis*).

➔ **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 Bactroban 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, pharmacist or nurse. This include 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.

How to store Bactroban

- Keep this medicine out of the sight and reach of children.
- Do not use Bactroban after the expiry date which is stated on the tube or carton after (EXP).
- Bactroban is an off-white, translucent ointment. Do not use it if it looks different to normal.
- Store as directed on the outer package.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Contents of the pack and other information

What Bactroban contains

- The active substance is mupirocin. Each gram of ointment contains 20 mg mupirocin.
- The other ingredients are polyethylene glycol 400 and polyethylene glycol 3350.

What Bactroban looks like and contents of the pack

- Bactroban is an off-white, translucent ointment.
- Bactroban is available in a 15 g tube. Each tube comes in a carton.

Bactroban is a trade mark of the GSK group of companies.

© 2017 GSK group of companies. All rights reserved.

Version number: HK022017(GDS15/MHRA201607)

包裝單張：使用者須知

Bactroban 軟膏 **Mupirocin free acid**

在使用本藥物前，請仔細閱讀本單張，因為其中包含重要資訊。

- 請保留此單張。您可能需要再次閱讀。
- 如您有任何進一步的疑問，請諮詢您的醫生，護士或藥劑師。
- 此藥物為醫生專門為您處方。請勿擅自將本藥物傳給他人服用。儘管他人的症狀和您一樣，但是還是可能會對他們造成損害
- 如果您出現了任何副作用 (包括本單張中未列出的任何可能的副作用)，請諮詢您的醫生，護士或藥劑師。

本單張中有哪些內容：

- 1 Bactroban 是什麼及有何用途
- 2 使用 Bactroban 前，您需要了解哪些資訊
- 3 如何使用 Bactroban
- 4 可能的副作用
- 5 如何存放 Bactroban
- 6 包裝內容和其他資訊

1. Bactroban 是什麼及有何用途

Bactroban 2% 軟膏 (本單張中被稱為“Bactroban”) 含有名為Mupirocin的活性成分。Bactroban是一種抗生素軟膏。

其用途有：

- 治療皮膚感染，例如
 - 毛囊感染，形成帶膿丘疹(“毛囊炎”(folliculitis))，
 - 一種具有傳染性的皮膚感染，伴有起泡和結痂，被稱為“膿疱病”(impetigo) 或
 - 複發性膿腫 (“癤病”(furunculosis))
- 該軟膏只供皮膚外用。

2. 使用 Bactroban 前，您需要了解哪些資訊

如有以下情況，切勿使用Bactroban：

- 如果您對Mupirocin 或本藥物中的任何其他成份有過敏反應 (在包裝內容和其他資訊中列出)。
- 如任何上述情況適用於您，請勿使用Bactroban。如果您不確定，切勿使用本藥物。請在使用Bactroban前諮詢您的醫生、護士或藥劑師。

警告和注意事項

- Bactroban會引發嚴重的皮膚反應或過敏症狀。請參見可能的副作用中‘您需要注意的情況’。
- 不可將Bactroban用於眼、鼻或圍繞靜脈插管(‘輸液’)部位。

如長期使用Bactroban，可能會引發鵝口瘡(酵母菌感染)。如果出現這種情況，請告知您的醫生、藥劑師或護士。

請避免讓軟膏接觸到眼睛。

- 如意外讓軟膏進入眼睛，請用清水徹底沖洗。

其他藥物與Bactroban

如果您正在使用，最近使用過或可能會使用任何其他藥物，請告知您的醫生、護士或藥劑師。

懷孕和哺乳

如果您已經懷孕或在哺乳期中，認為您可能懷孕或計劃懷孕，請在使用本藥物前諮詢您的醫生或藥劑師。

如果正在治療乳頭破裂，請切記在哺乳前徹底洗掉軟膏。

駕駛和使用機器

Bactroban不會對駕駛和操作機器產生影響。

Bactroban軟膏含有聚乙二醇 (Polyethylene glycol)

如果您有以下情況，請在使用本藥物前諮詢您的醫生：

- 如您患有腎病
- 如您有大面積開放性創傷或需要治療的受損皮膚

3. 如何使用 Bactroban

請嚴格按照醫生或藥劑師指示用藥。如果您有不明白的地方，請諮詢您的醫生或藥劑師。

使用本藥物

切勿將Bactroban與任何其他外用乳膏或軟膏類藥物混合用於皮膚受感染處，這可能會降低Bactroban的藥效。

一般情況下，您每天要在皮膚上使用Bactroban 2到3次。

1. 清洗並擦乾雙手。
2. 將軟膏塗抹到受感染的皮膚處。
3. 您可以用硬膏或適當的敷料覆蓋接受治療的地方，除非您的醫生告訴你不要。
4. 放回軟管上的蓋子並清洗雙手。

Bactroban 應該使用多長時間？

請按照醫生指示使用Bactroban。如果您不確定，請諮詢您的醫生、護士或藥劑師。在開始治療後的10天內，皮膚上的細菌一般就會被清除了。切勿使用Bactroban超過10天。請將剩餘的軟膏扔掉。

如果您吞服了Bactroban

如果您誤服了軟膏，請告知您的醫生、護士或藥劑師，尋求他們的建議。

如果您忘記使用Bactroban

- 如果您忘記使用Bactroban，請在記起時立即使用。
- 如果您即將在1小時內進行下一次用藥，那麼請忽略掉錯過的用藥。
- 請勿因為忘記用藥而一次使用雙倍劑量。

如果您停止使用Bactroban

如果您過早停用Bactroban，則可能無法殺滅所有細菌或這些細菌會繼續生長。請諮詢您的醫生、護士或藥劑師，了解何時停用此軟膏。

如果您對該藥物的使用有任何進一步的疑問，請諮詢您的醫生、護士或藥劑師。

4. 可能的副作用

和所有藥物一樣，本品也會導致一些副作用，儘管並非所有人都出現這些症狀。

您需要注意的情況

嚴重的皮膚反應或過敏：

這在使用Bactroban的患者中極為罕見。跡象包括：

- 凸起且痕癢的皮疹
 - 腫脹，有時出現在面部或嘴部，造成呼吸困難
 - 暈倒或失去意識。
- ➔ 如果您出現任何這些症狀，請立即聯絡您的醫生。停止使用Bactroban。

- 如果您出現了嚴重的皮膚反應或過敏症狀：
 - 將軟膏清洗乾淨
 - 停止用藥並
 - 請盡快就醫。

在罕見的情況下，像Bactroban這樣的藥物會造成結腸（大腸）發炎，從而造成腹瀉，通常會伴有出血和黏液，胃痛和發燒（*假膜性結腸炎(pseudomembranous colitis)*）。

➔ 如果您出現任何這些症狀，請立即聯絡您的醫生。

本藥物可能會產生以下副作用：

常見（每10個人中最多有1人可能會受此影響）：

- 軟膏塗抹處有燒灼感。

不常見（每100個人中最多有1人可能會受此影響）：

- 在使用(Bactroban)的患處出現痕癢、發紅、刺痛和乾燥的情況。
- 身體其他部位皮膚也可能會出現過敏性皮炎、痕癢、發紅或疼痛的情況。

極為罕見（每10,000個人中最多有1人可能會受此影響）

- 面部腫大和/或呼吸困難。這可能是嚴重的過敏反應，可能需要緊急治療。

報告副作用

如果您出現了任何副作用，請諮詢您的醫生、藥劑師或護士。這包括未在本單張中列出的任何可能的副作用。

通過報告副作用，您能夠幫助提供有關本藥物的更多安全資訊。

5. 如何存放 Bactroban

- 請將本藥物放在兒童無法看見並觸及的地方。
- 如果Bactroban過了藥膏管和包裝盒上的到期日，切勿使用。
- Bactroban為近似白色、半透明的軟膏。如果藥物外觀出現異常，切勿使用。
- 請參考外包裝註明的存放條件。
- 切勿通過廢水或家庭垃圾丟棄任何藥物。請諮詢您的藥劑師，了解如何處理不用的藥物。這些措施有助於保護環境。

6. 包裝內容和其他資訊

Bactroban的成份

- 活性成份是Mupirocin。每克軟膏含有20毫克Mupirocin。
- 其他成份為polyethylene glycol 400和polyethylene glycol 3350。

Bactroban的外觀和包裝內容

- Bactroban為近似白色、半透明的軟膏。
- Bactroban使用的是15克的管狀包裝。每支軟膏都有一個紙盒包裝。

Bactroban是葛蘭素史克集團所擁有的註冊商標。

© 2017 葛蘭素史克集團版權所有。

版本編號：HK022017(GDS15/MHRA201607)