

## **Bactroban Nasal Ointment**

**Mupirocin calcium**

### **Qualitative and quantitative composition**

Mupirocin calcium equivalent to 2% w/w mupirocin free acid in a white soft paraffin based ointment.

### **Pharmaceutical Form**

Nasal ointment.

### **Clinical Particulars**

#### **Indications**

Elimination of nasal carriage of staphylococci, including methicillin resistant *Staphylococcus aureus* (MRSA).

#### **Dosage and Administration**

##### **Adults (including the elderly/renally impaired/hepatically impaired) and Children:**

Apply a small quantity of Mupirocin nasal ointment, about the size of a match head (approximately 30 mg of ointment) to each nostril two to three times a day for at least 5 days.

#### **Method of Administration**

Use a cotton tipped applicator. After application, the nostrils should be closed by pressing the sides of the nose together several times.

Nasal carriage should normally be clear within 5-7 days of treatment.

Dosage should not exceed ten days.

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

#### **Contraindications**

Hypersensitivity to mupirocin or any of the excipients (see **List of Excipients**).

#### **Special warnings and precautions for use**

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

As with other antibacterial products, prolonged use may result in overgrowth of non-susceptible 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.

This mupirocin nasal ointment formulation is not suitable for ophthalmic use.

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.

### **Effects on ability to drive and use machines**

No adverse effects on the ability to drive or use machinery may have been observed.

### **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.

Uncommon adverse reactions were determined from pooled safety data from a clinical trial population of 422 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: Cutaneous hypersensitivity reactions. Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema.

#### *Respiratory, thoracic and mediastinal disorders*

Uncommon: Nasal mucosa reactions.

### **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** White soft paraffin, Softisan.

**Incompatibilities** None reported.

### **Instructions for Use/Handling**

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

Trade marks are owned by or licensed to the GSK group of companies  
© 2017 GSK group of companies or its licensor

Version number: HK022017(GDS15UKSPC20170119)

**Package Leaflet: Information for the user**  
**Bactroban 2% Nasal Ointment**  
**mupirocin calcium**

**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

**1 What Bactroban is and what it is used for**

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

It is used:

- to kill a group of bacteria in the nose called 'Staphylococci'
- this group includes MRSA (Methicillin Resistant *Staphylococcus aureus*)
- this ointment is for use in your nose only.

**2 What you need to know before you use Bactroban**

**Do not use Bactroban:**

- if you are allergic (hypersensitive) to mupirocin calcium, mupirocin or any of the other ingredients of this medicine (listed in section 6).

If you are not sure if this applies to you, 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 Section 4.

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.

## Driving and using machines

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

## 3 How to use Bactroban

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

### Using this medicine

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

- 1 Wash and dry your hands.
- 2 Place a small amount of Bactroban, about the size of a match head, on your little finger.
- 3 Apply this to the inside of one nostril.
- 4 Repeat steps 2 and 3 for your other nostril.
- 5 Press the sides of your nose together to spread the ointment around the nostril.
- 6 Replace the cap on the tube and wash your hands.

A cotton bud can be used instead of your little finger to apply the ointment, particularly in infants or the very ill.

### 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 nose within 5 to 7 days of starting treatment.

### 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.

## 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 Bactroban. 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:

**Uncommon** (may affect up to 1 in 100 people)

- Itching, redness, burning, tingling or stinging of the nose.

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

- Some people can develop a skin reaction or allergy that is severe. The signs can include a rash, itchiness, redness or soreness.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 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 smooth ointment. Do not use it if it looks different to normal.
- Store as directed on the outer package.

## **6 Contents of the pack and other information**

### **What Bactroban contains**

- The active substance is mupirocin calcium. Each gram of nasal ointment contains mupirocin calcium equivalent to 20 mg mupirocin.
- The other ingredients are white soft paraffin and Softisan 649.

### **What Bactroban looks like and contents of the pack**

- Bactroban is a smooth off-white ointment.
- Bactroban is available in a 3g tube. Each tube comes in a carton.

Trade marks are owned by or licensed to the GSK group of companies.

© 2017 GSK group of companies or its licensor.

Version number: HK022017 (GDS15/MHRA201607)

## 包裝單張：使用者須知

### **Bactroban Nasal 軟膏 mupirocin calcium**

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 (請參見 *可能的副作用*，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% Nasal 軟膏 (本單張中被稱為“Bactroban”) 含有名為 Mupirocin Calcium 的活性成分。Bactroban 是一種抗生素軟膏。

其用途有：

- 殺滅鼻子內一種稱為“葡萄球菌” (Staphylococci) 的細菌
- 此種細菌包括 MRSA (Methicillin Resistant *Staphylococcus aureus*)
- 此軟膏只適用您的鼻子。

#### 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 Calcium, 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’。

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。

## 駕駛和使用機器

Bactroban不會對駕駛和操作機器產生影響。

### 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

一般情況下，您每天在你的鼻子應用Bactroban 2到3次。

1. 清洗並擦乾雙手。
2. 在你的小指上放置少量的Bactroban，大約火柴頭般大小。
3. 將其塗抹於一個鼻孔的內側。
4. 對您的另一鼻孔重複步驟2和3。
5. 按壓鼻子的兩側，使軟膏塗抹在鼻孔周圍。
6. 放回軟管上的蓋子並清洗雙手。

可以使用棉花棒代替你的小指塗抹軟膏，特別是在嬰兒或病重的病人。

#### 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5-7天內，鼻子內的細菌一般就會被清除掉。

#### 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，本藥品也會導致一些副作用，儘管並非所有人都會出現這些症狀。

#### 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(*psuedomembranous 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：

不常見（每100個人中最多有1人可能會受此影響）：

- 鼻子出現痕癢，發紅，燃燒，麻刺感或刺痛。

極為罕見（每10,000個人中最多有1人可能會受此影響）

- 有些人可能發展為嚴重的皮膚反應或過敏。跡象可以包括皮疹，痕癢，發紅或酸痛。

### 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。

### 6. 包裝內容和其他資訊

#### Bactroban的成份

- 活性成份是Mupirocin Calcium。每克軟膏含有20毫克Mupirocin。
- 其他成份為 white soft paraffin 和 Softisan 649。

#### 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3克的管狀包裝。每支軟膏都有一個紙盒包裝。

商標為葛蘭素史克集團擁有或經授權使用。

© 2017 葛蘭素史克集團或其授權人。

版本編號：HK022017(GDS15/MHRA201607)