

## 1. NAME OF THE MEDICINAL PRODUCT

**Macroban Cream (Mupirocin 2%)**

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each TUBE

MUPIROCIN(MUPIROCIN 2%).....15g

For the full list of excipients, see section 6.1

## 3. Pharmaceutical form

Cream.

Macroban Cream is presented as a white cream of homogeneous appearance

## 4. Clinical particulars

### 4.1 Therapeutic indications

Mupirocin is indicated in adults and children.

Macroban contains an active called Mupirocin. Mupirocin is an antibiotic cream.

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)
- To kill various bacteria which cause other skin infections including *Staphylococci*, *Streptococci* and *E. coli*. This group includes MRSA (Methicillin Resistant *Staphylococcus aureus*).
- This cream is for external use on your skin only.

### 4.2 Posology and method of administration

#### Posology

Use Macroban<sup>®</sup>(Mupirocin 2%) Cream exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

Mupirocin Cream should be applied to the affected area up to three times a day for up to 10 days. The area may be covered with a dressing or occluded, unless the doctor has told you to leave it uncovered.

Replace the cap on the tube and wash your hands.

Use Mupirocin cream for as long as your doctor has told you.

Throw away any cream that is left over.

#### Method of administration

Topical.

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 cream.

If you are using Mupirocin cream on your face, you should be careful not to get it in your eyes or in your nose. If you accidentally get Mupirocin cream in your eyes, wash them thoroughly with water and contact your doctor or nearest hospital.

#### **If you use more Macroban®(Mupirocin 2%) Cream than you should**

If you use more Mupirocin Cream than your doctor prescribed, tell your doctor, pharmacist or nurse.

If you or a child accidentally swallows Mupirocin Cream, you should contact your doctor or the nearest hospital.

#### **If you forget to use Macroban®(Mupirocin 2%) Cream**

Don not worry, use the cream when you remember and then carry on as normal. If your next dose is due within an hour, skip the missed dose.

Do not apply double the amount to make up for the amount missed.

#### **If you stop using Macroban®(Mupirocin 2%) Cream**

If you stop using Mupirocin Cream too early, not all of the bacteria causing your skin infection may have been killed and your infection may come back. Ask your doctor, pharmacist or nurse when to stop using the cream.

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

#### **4.3 Possible Side Effects**

Like all medicines, Macroban®(Mupirocin 2%) Cream can cause side effects, although not everybody gets them.

All drugs may cause side effects. However, many people have no side effects, only few people have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away.

- Burning or stinging
- Itching
- Headache
- Upset stomach.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

#### **4.4 Contraindications**

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 This Mupirocin Cream formulation is not suitable for ophthalmic or intranasal use.

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

Should a possible sensitisation reaction or severe local irritation occur with the use of Macroban Cream, 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 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.

Macroban Cream formulation is not suitable for ophthalmic use and intranasal use.

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

Macroban Cream contains cetyl alcohol and stearyl alcohol. These inactive ingredients may cause local skin reactions (e.g. contact dermatitis).

Macroban Cream also contains 153 mg benzyl alcohol in each 15 g tube. This inactive ingredient may cause mild local irritation.

#### **4.6 Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed.

#### **4.7 Fertility, pregnancy and lactation**

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

**Breast-feeding:** It is unknown whether Mupirocin is excreted in human milk. If a cracked nipple is to be treated, it should be thoroughly washed prior to breast-feeding.

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

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

Macroban Cream has no or negligible influence on the ability to drive and use machines.

#### **4.9 Adverse effect/side effects**

Like all medicines, Macroban® (Mupirocin 2%) Cream can cause side effects, although not everybody gets them.

All drugs may cause side effects. However, many people have no side effects, only few people have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away.

- Burning or stinging
- Itching
- Headache
- Upset stomach.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

#### **4.10 Undesirable effects**

Data from clinical trials was used to determine the frequency of very common to rare undesirable effects. Very rare adverse reactions were primarily determined from post-marketing experience data - and therefore refer to reporting rate rather than true frequency.

The following convention has been used for the classification of frequency:-

very common  $\geq 1/10$ , common  $\geq 1/100$  and  $< 1/10$ , uncommon  $\geq 1/1000$  and  $< 1/100$ , rare  $\geq 1/10,000$  and  $< 1/1000$ , very rare  $< 1/10,000$ .

*Immune system disorders:*

Very rare: Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema

*Skin and subcutaneous tissue disorders:*

Common: Application site hypersensitivity reactions including urticaria, pruritus, erythema, burning sensation, contact dermatitis, rash

Skin dryness and erythema have been reported in irritancy studies in volunteers.

#### **4.11 Overdose**

##### **Symptoms**

There is currently limited experience with overdosage of Mupirocin.

##### **Management**

The toxicity of Mupirocin is very low. In the event of accidental ingestion of the ointment, symptomatic treatment should be given.

In case of erroneous oral intake of large quantities of the ointment, renal function should be closely monitored in patients with renal insufficiency because of the possible side effects of polyethylene glycol.

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.

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Dermatologicals ATC code: D06AX09, Antibiotics and chemotherapeutics for dermatological use

##### Mechanism of action

Mupirocin is a novel antibiotic produced through fermentation by *Pseudomonas fluorescens*. Mupirocin inhibits isoleucyl transfer-RNA synthetase, thereby arresting bacterial protein synthesis.

Mupirocin has bacteriostatic properties at minimum inhibitory concentrations and bactericidal properties at the higher concentrations reached when applied locally.

##### Mechanism of resistance

Low-level resistance in staphylococci is thought to result from point mutations within the usual staphylococcal chromosomal gene (ileS) for the target isoleucyl tRNA synthetase enzyme. High-level

resistance in staphylococci has been shown to be due to a distinct, plasmid encoded isoleucyl tRNA synthetase enzyme.

Intrinsic resistance in Gram negative organisms such as the *Enterobacteriaceae* could be due to poor penetration of the outer membrane of the Gram-negative bacterial cell wall.

Due to its particular mode of action, and its unique chemical structure, mupirocin does not show any cross-resistance with other clinically available antibiotics.

### Microbiological susceptibility

The prevalence of acquired resistance may vary geographically and with time for selected species, and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infection is questionable.

<b>Commonly susceptible species</b>
<i>Staphylococcus aureus</i> *
<i>Streptococcus pyogenes</i> *
<i>Streptococcus</i> spp. ( $\beta$ -haemolytic, other than <i>S. pyogenes</i> )
<b>Species for which acquired resistance may be a problem</b>
<i>Staphylococcus</i> spp., coagulase negative
<b>Inherently resistant organisms</b>
<i>Corynebacterium</i> spp.
<i>Micrococcus</i> spp.

\* Activity has been satisfactorily demonstrated in clinical studies

## **5.2 Pharmacokinetic properties**

### Absorption

Systemic absorption of mupirocin through intact human skin is low although it may occur through broken/diseased skin. However, clinical trials have shown that when given systemically, it is metabolised to the microbiologically inactive metabolite monic acid and rapidly excreted.

### Elimination

Mupirocin is rapidly eliminated from the body by metabolism to its inactive metabolite monic acid which is rapidly excreted by the kidney.

## **5.3 Preclinical safety data**

Pre-clinical effects were seen only at exposures which are extremely unlikely to cause concern for humans under normal conditions of use. Mutagenicity studies revealed no risks to man.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Xanthan gum  
Liquid paraffin  
Cetomacrogol 1000  
Cetostearyl alcohol  
Propylene glycol  
Benzyl alcohol  
Purified water

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

18 months

### **6.4 Special precautions for storage**

Do not store above 25°C. Do not freeze.

### **6.5 Nature and contents of container**

Squeezable aluminium tubes with a screw cap containing 15 g of white cream.

### **6.6 Special precautions for disposal and other handling**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Wash your hands after application.

## **7.0 APPLICANT/MANUFACTURER**

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