Public Assessment Report

Decentralised Procedure

Mupirocin InfectoPharm 20 mg/g ointment

(mupirocin)

Procedure No: UK/H/5763/001/DC

UK Licence No: PL 15011/0016

INFECTOPHARM Arzneimittel und Consilium GmbH
LAY SUMMARY
Mupirocin InfectoPharm 20 mg/g ointment
(mupirocin)

This is a summary of the Public Assessment Report (PAR) for Mupirocin InfectoPharm 20 mg/g ointment (PL 15011/0016; UK/H/5763/001/DC). This product will be referred to as Mupirocin in the remainder of this summary, for ease of reading.

This summary explains how Mupirocin was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

For practical information about using Mupirocin, patients should read the package leaflet or contact their doctor or pharmacist.

What is Mupirocin and what is it used for?
The application for Mupirocin was submitted as a hybrid application. Assessment of the application concluded that the ointment is similar to a reference medicine containing the same active substance (mupirocin) in the same dose.

The reference medicine for Mupirocin is Bactroban 2% ointment (PL 00038/0319; Beechams Group PLC).

This medicine is used in adults, adolescents, children and infants aged 8 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 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).

How does Mupirocin work?
Mupirocin contains the active ingredient mupirocin which belongs to a group of medicines called antibiotics. This medicine is an antibiotic ointment for external use on the skin only.

How is Mupirocin used?
The pharmaceutical form of this medicine is an ointment. Usually Mupirocin is applied to the affected area of the skin 2 to 3 times a day.

The bacteria are normally cleared from the skin within 10 days of starting treatment. This medicine should not be used for more than 10 days. Patients must consult a doctor if their skin condition does not improve within 3 to 5 days. Any left over ointment should be thrown away.

This medicinal product can only be obtained with a prescription from a doctor.

For further information on how Mupirocin is used, please see the Summary of Product Characteristics or the package leaflet available on the MHRA website.

What benefits of Mupirocin have been shown in studies?
Because Mupirocin is considered to be therapeutically equivalent to the reference product Bactroban 2% ointment, its benefits and risks are taken as being the same as those of the reference medicine.

**What are the possible side effects of Mupirocin?**
Like all medicines, this medicine can cause side effects, although not everybody gets them.

The common side effect with Mupirocin (which may affect up to 1 in 10 people) is burning where the ointment is applied.

For the full list of restrictions, see the package leaflet.

For the full list of all side effects reported with Mupirocin, see section 4 of the package leaflet available on the MHRA website.

**Why was Mupirocin approved?**
The MHRA decided that Mupirocin’s benefits are greater than its risks and recommended that it be approved for use.

**What measures are being taken to ensure the safe and effective use of Mupirocin?**
A risk management plan (RMP) has been developed to ensure that Mupirocin is used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for Mupirocin including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously.

**Other information about Mupirocin**
Italy, Poland and the UK agreed to grant a Marketing Authorisation for Mupirocin on 19 January 2016. A Marketing Authorisation was granted in the UK on 10 February 2016.

The full PAR for Mupirocin follows this summary.

For more information about treatment with Mupirocin, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in March 2016.
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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy the Member States considered that the application for Mupirocin InfectoPharm 20 mg/g ointment (PL 15011/0016; UK/H/5763/001/DC), could be approved.

The product is a prescription-only medicine (POM) and is a topical antibacterial agent, active against those organisms responsible for the majority of skin infections, e.g. *Staphylococcus aureus*, including methicillin-resistant strains, other staphylococci, streptococci. It is also active against Gram-negative organisms such as *Escherichia coli* and *Haemophilus influenzae*. Mupirocin InfectoPharm is used for skin infections, e.g. impetigo, folliculitis, furunculosis in adults, adolescents, children and infants aged 8 weeks and older.

The application was submitted using the Decentralised Procedure (DCP), with the UK as Reference Member State (RMS) and Italy and Poland as Concerned Member States (CMSs). The application was submitted under Article 10.3 of Directive 2001/83/EC, as amended, as a hybrid application. The reference medicinal product for this application is Bactroban 2% Ointment which was first authorized in the UK to Beecham Group Plc on 26 March 1985.

The medicinal product contains the active substance, mupirocin. 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.

No new non-clinical studies were conducted, which is acceptable given that this is a hybrid application cross-referring to a product that has been licensed for over 10 years.

To support the application, the Marketing Authorisation Holder (MAH) submitted a therapeutic equivalence study to compare the test product Mupirocin InfectoPharm 20 mg/g ointment (Infectopharm Arzneimittel und Consilium GmbH) and the reference product Bactroban 2% Ointment (Beecham Group Plc). The study was carried out in accordance with Good Clinical Practice (GCP).

The RMS has been assured that acceptable standards of Good Manufacturing Practice are in place for this product type at all sites responsible for the manufacture, assembly and batch release of this product.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

All Member States agreed to grant a Marketing Authorisation for the above product at the end of the procedure (Day 210 – 19 January 2016). After a subsequent national phase, the UK granted a Marketing Authorisation (PL 15011/0016) for this product on 10 February 2016.
II QUALITY ASPECTS

II.1 Introduction

This product is an ointment and contains 20 mg/g mupirocin as the active ingredient.

Other ingredients consist of the pharmaceutical macrogol 400 and macrogol 3350. Appropriate justification for the inclusion of each excipient has been provided.

All excipients comply with their respective European Pharmacopoeia monographs.

None of the excipients contain materials of animal or human origin.

The finished product is packed in aluminium tubes closed with polypropylene screw cap. The pack sizes are 5 g, 2 x 5 g, 3 x 5 g, 15 g and 2 x 15 g.

Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current European regulations concerning materials in contact with food.

II.2 Drug Substance

INN: Mupirocin

Structural formula:

```
OH
O
HO
H
O
```

Molecular formula: C_{26}H_{44}O_{9}
Molecular mass: 500.63 g/mol
Appearance: Mupirocin is a white or almost white powder.
Solubility: Mupirocin is slightly soluble in water, freely soluble in acetone, anhydrous ethanol and methylene chloride.

Mupirocin is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance, mupirocin, are covered by European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificates of Suitability.

II.3 Medicinal Product

Pharmaceutical Development

The objective of the development programme was to formulate a stable topical preparation (ointment) that is comparable in performance to the reference product Bactroban 2% Ointment (Beecham Group Plc).

A satisfactory account of the pharmaceutical development has been provided.
Comparative physico-chemical and impurity profiles have been provided for the proposed and originator products.

**Manufacture of the product**
A satisfactory batch formula has been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results. Process validation data on commercial scale batches have been provided.

**Finished Product Specification**
The finished product specification proposed is acceptable. The test methods that have been described have been adequately validated. Batch data have been provided that comply with the release specifications.

**Stability of the Product**
Finished product stability studies were performed in accordance with current guidelines on batches of finished product in the packaging proposed for marketing. The data from these studies support a shelf life of 2 years for unopened tubes which reduces to 10 days once opened. The storage conditions are ‘Store below 25°C’.

**Therapeutic Equivalence**
Bioequivalence studies are not necessary to support this application. For products for local application intended to act without systemic absorption, the approach to determine equivalence on systemic measurements is not applicable and pharmacodynamics or comparative clinical studies are required. The applicant has submitted one clinical study to establish therapeutic equivalence between the proposed product and the reference product. This study is discussed in Section IV.

**II.4 Discussion on chemical, pharmaceutical and biological aspects**
There are no objections to the approval of this application from a pharmaceutical point of view.

**III NON-CLINICAL ASPECTS**
**III.1 Introduction**
The pharmacodynamic, pharmacokinetic and toxicological properties of mupirocin are well-known. As this is a widely used, well-known active substance, the applicant has not provided additional studies and further studies are not required. An overview based on literature review is, thus, appropriate.

The non-clinical overview has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

**III.2 Pharmacology**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.3 Pharmacokinetics**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.4 Toxicology**
Not applicable for this product type. Refer to section ‘III.1; Introduction’ detailed above.

**III.5 Ecotoxicity/environmental risk assessment (ERA)**
Since this product is intended for substitution of an originator product, this will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.
III.6 Discussion on the non-clinical aspects
There are no objections to the approval of this application from a non-clinical point of view.

IV CLINICAL ASPECTS
IV.1 Introduction
The clinical pharmacology of mupirocin is well-known. With the exception of the clinical study detailed below, no new pharmacodynamics or pharmacokinetic data are provided or required for this application.

IV.2 Pharmacokinetics
No new pharmacokinetic data were submitted and none are required for applications of this type.

IV.3 Pharmacodynamics
No new pharmacodynamic data were submitted and none are required for applications of this type.

IV.4 Clinical efficacy
In support the application, the applicant has submitted the following therapeutic equivalence study.

A multi-centre, prospective, randomized, controlled, double-blind study to compare the test product Mupirocin Infectopharm 20 mg/g Ointment (InfectoPharm Arzneimittel und Consilium GmbH) with the reference product Bactroban 2% Ointment (Beecham Group Plc) in children with impetigo.

Both the products contained the active ingredient mupirocin 2% and were applied three times per day for 7 consecutive days. The children were followed up for 7 days after end of treatment.

Objectives
The primary objective of the study is to prove that the generic test preparation Mupirocin Infectopharm 20 mg/g Ointment is statistically equivalent to the original preparation Bactroban® ointment 2% with respect to the proportion of patients who are clinically cured at the final visit (Day 14, 7 days after the end of a 7-day treatment).

Secondary objectives include the investigation of further aspects of efficacy (e.g. microbiological cure) and safety (e.g. adverse drug reactions).

Methodology
Children aged between 28 days and 15 years with clinically diagnosed impetigo and a skin infection rating scale (SIRS) of 4 or more with 3 or more SIRS signs/symptoms being positive. In addition, an initial swab from the affected region should be positive for detection of *staphylococcus aureus* and/or *streptococcus pyogenes*.

Both ointments are to be applied topically in thin layers on the affected parts of the skin, three times a day for 7 consecutive days.

Outcomes/endpoints

Primary efficacy variable:
Clinical cure rate at Day 14, defined as the percentage of patients who fulfil all of the following properties:
- No need for further antibiotic therapy of impetigo
- SIRS score = 0 (absent) for signs/symptoms blistering and exudate/pus
- SIRS score ≤ 1 (absent or mild) for signs/symptoms crusting, erythema/inflammation and itching/pain
Secondary efficacy variables:
- Microbiological cure rate at Day 14, defined as the percentage of patients with negative result regarding both *staphylococcus aureus* and *streptococcus pyogenes* in the bacteriological swab
- Clinical cure rate at Day 7 (defined analogous to the primary efficacy variable)
- Microbiological cure rate at Day 7
- Percentage of patients with premature discontinuation at Day 3 due to lack of efficacy
- SIRS total score values at Day 7 and Day 14
- Changes in SIRS total score between Day 0 and Day 7, Day 0 and Day 14, and between Day 7 and Day 14

Safety
- Number and classification of adverse events and adverse drug reactions (ADRs).
- Premature discontinuations

Testing for equivalence of the two treatment groups with respect to the primary efficacy variable in accordance with the FDA Draft Guidance on Mupirocin. Confirmatory analysis is based on the per-protocol data set.

The test of equivalence is based on the following (two-sided) hypotheses:

\[ \text{H}_0: p_{\text{Mupirocin}} - p_{\text{Bactroban}} < -0.20 \text{ or } p_{\text{Mupirocin}} - p_{\text{Bactroban}} > 0.20 \text{ versus } \]
\[ \text{H}_1: -0.20 \leq p_{\text{Mupirocin}} - p_{\text{Bactroban}} \leq 0.20 \]

Where:
\[ p_{\text{Mupirocin}} = \text{clinical cure rate at Day 14 after start of treatment with Mupirocin Infectopharm} \]
\[ p_{\text{Bactroban}} = \text{clinical cure rate at Day 14 after start of treatment with Bactroban} \]

According to the method of Westlake a two-sided 90% confidence interval is calculated for the difference in observed cure rates. Statistical equivalence is proven, if the confidence interval lies entirely inside the interval \([-0.20 ; 0.20]\).

All other statistical tests are exploratory. The tests will be carried out two-sided with the nominal significance level \(\alpha = 0.05\). The corresponding (two-sided) 95% confidence intervals will also be provided. The secondary efficacy variables will be analysed for both the intention to treat (mITT) and per protocol (PP) data sets.

Results

**Primary efficacy variable:**
The clinical cure rate at Day 14 for the PP data set was 1.0 (100.0%) for Mupirocin Infectopharm and 0.95 (95.0%) for Bactroban according to the predefined criteria. As the 90% confidence interval \([-0.01 ; 0.11]\) for the difference in cure rates was entirely inside the interval \([-0.20 ; 0.20]\), recommended by the FDA Draft Guidance on Mupirocin, statistical equivalence of both medications was proven. This result was confirmed by the corresponding analysis for the mITT data set.

With the exception of 3 patients in the Bactroban group, all patients were clinically cured. Two of these 3 patients terminated the study at Day 3 and Day 7 respectively because of treatment failure and one patient had a SIRS score value 1 (=mild) for the symptom exudate/pus.

**Secondary efficacy variables:**
Secondary efficacy variables were analysed based on the modified ITT data set and confirmed by PP analysis.
The microbiological cure at Day 14 (negative result for both staphylococcus aureus and streptococcus pyogenes in the bacteriological swab) is demonstrated for 100% (56 patients) under Mupirocin Infectopharm and 98.4% (61 patients) for the reference product.

At Day 7, 73.2% (41 patients) for the test and 69.8% (44 patients) for the reference fulfilled the criterion for clinical cure. At Day 7, 85.7% (48 patients) in the test group and 91.9% (57 patients) in the reference product group fulfilled the criterion for microbiological cure.

Only 1.6% (1 patient) in the reference product group discontinued the study at Day 3 due to lack of efficacy.

The mean baseline values of the SIRS total score were 8.7 in both treatment groups. At Day 7, the mean was 1.5 in the test group and 1.7 in the reference product group. Until Day 14, the values further decreased to 0.3 in the test group and to 0.7 in the reference group. The group differences were not statistically significant.

The mean total score in the SIRS at Day 7 compared to baseline decreased by 7.2 for test and 7.0 for reference product. In the 7 days after the end of the treatment phase further reduction of the average scores was observed by 1.2 for the test product and 1.0 for the reference product. There were no statistically significant differences between the two treatment groups.

Results of efficacy study:

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Treatment arm</th>
<th># Enrolled / completed</th>
<th>Primary Endpoint (Clinical cure on Day 14, IFP pop.)</th>
<th>Statistical test / result</th>
<th>Microbiol. cure on Day 14</th>
<th>Clinical cure on Day 7</th>
<th>Microbiol. cure on Day 7</th>
<th>Premature discontinuation on Day 3 due to lack of efficacy</th>
<th>Mean SIRS total score on Day 6, Day 7, and Day 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>MUP</td>
<td>Mupirocin Infectopharm 20 mg/g Ointment</td>
<td>153 (75/78) (enrolled); 150 (75/75) (SE pop.); 119 (56/63) (ITT pop.); 113 (55/60) (FP pop.)</td>
<td>100% (Mupirocin Infectopharm 20 mg/g Ointment); 95% CI of the difference in cure rates [0.01; +0.11] lies entirely within the interval [-0.20; +0.20]; Mupirocin Infectopharm 20 mg/g Ointment and Bactroban® Ointment 2% are therapeutically equivalent</td>
<td>100.0% (Mupirocin Infectopharm 20 mg/g Ointment); 98.4% (Bactroban® Ointment 2%); 95% CI of the difference in rates [-0.03; +0.06]</td>
<td>73.2% (Mupirocin Infectopharm 20 mg/g Ointment); 69.8% (Bactroban® Ointment 2%); 95% CI of the difference in rates [-0.15; +0.21]</td>
<td>85.7% (Mupirocin Infectopharm 20 mg/g Ointment); 91.9% (Bactroban® Ointment 2%); 95% CI of the difference in rates [-0.19; +0.07]</td>
<td>0% (Mupirocin Infectopharm 20 mg/g Ointment); 1.6% (Bactroban® Ointment 2%); 95% CI of the difference in rates [-0.06; +0.03]</td>
<td>8.7 (Day 6); 1.5 (Day 7); 0.3 (Day 14); 0.7 (Day 6); 0.7 (Day 7); 0.7 (Day 14)</td>
<td>Bactroban® Ointment 2%</td>
</tr>
</tbody>
</table>

Safety results:
Overall, adverse events (AEs) were reported for 17 patients (test product: 5, reference product: 12). The total number of events was 28 (test product: 11, reference product: 17).

All AEs were mild to moderate and there were no serious adverse events (SAEs) and no dropouts due to AEs.

Conclusion
The study met its pre-specified primary endpoint and thus concluded that the test product was therapeutically equivalent to the reference product. From a statistical perspective, it would normally be expected for the 95% CI (not 90% CI) to be reported. The applicant has stated that the 95% CI is equal to (-0.023; 0.123). These limits are also within the pre-specified (-0.20; 0.20) limits and therefore the study can be accepted as a success. For the justification of the proposed margin for difference, the direction of the difference suggests that the test product is likely to have a slightly higher efficacy than...
the reference, based on the results of the study. Therefore there are no concerns on the efficacy. For a product like mupirocin which is poorly permeable and literally no significant systemic exposure, the likely upper limit of the difference between the products of 12% does not raise concerns on safety either. Therefore the proposed limit of 20% difference for the study is acceptable and the study can be considered to demonstrate therapeutic equivalence as pre-specified.

### IV.5 Clinical safety

The safety profile of mupirocin is well-known. With the exception of the safety data generated during the therapeutic equivalence study, no new safety data were submitted and none are required for this type of application. No new or unexpected safety issues arose during the therapeutic equivalence study. The proposed product has shown therapeutic equivalence to the reference product with no safety concerns raised.

### IV.6 Risk Management Plan (RMP)

The Marketing Authorisation Holder (MAH) has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Mupirocin InfectoPharm 20 mg/g ointment.

A summary of safety concerns and planned risk minimisation activities, as approved in the RMP, is listed below:

<table>
<thead>
<tr>
<th>Important identified risks</th>
<th>Routine risk minimisation measures</th>
<th>Additional risk minimisation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety concern</td>
<td>Routine risk minimisation measures</td>
<td>Additional risk minimisation measures</td>
</tr>
<tr>
<td>Hypersensitivity to mupirocin or to any of its excipients</td>
<td>Information on “hypersensitivity to mupirocin or to any of its excipients” is mentioned in the SmPC (section 4.3 and 4.4) and patient information leaflet (section 2).</td>
<td>Not necessary</td>
</tr>
<tr>
<td>Adverse reactions or risks arising from excipients (e.g. polyethylene)</td>
<td>Information on “adverse reactions or risks arising from excipients (e.g. polyethylene)</td>
<td>Not necessary</td>
</tr>
</tbody>
</table>
from excipients (polyethylene glycol), especially when applied to open wounds or damaged skin and in patients with renal impairment. "glycol)" are mentioned and explained in the SmPC (section 4.4) and patient information leaflet (section 2).

Information on "use in renal impairment" is mentioned in the summary of product characteristics (section 4.2) and patient information leaflet (section 2).

### Important potential risks

<table>
<thead>
<tr>
<th>Safety concern</th>
<th>Routine risk minimisation measures</th>
<th>Additional risk minimisation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of resistance</td>
<td>Information on &quot;development of resistance&quot; is mentioned in the SmPC (section 5.1). To avoid formation of resistance recommendations how to use mupirocin are given in the summary of product characteristics (section 4.2) and patient information leaflet (section 3).</td>
<td>Not necessary</td>
</tr>
<tr>
<td>Medication errors: Wrong administration (oral intake, ophthalmic use, intranasal use, use in conjunction with cannulae, use at the site of central venous cannulation)</td>
<td>Information on &quot;oral intake of MUPIROCIN 20 mg/g ointment&quot; is mentioned in the summary of product characteristics (section 4.9) and patient information leaflet (section 3). Warnings of &quot;ophthalmic use, intranasal use, use in conjunction with cannulae and at the site of central venous cannulation&quot; are addressed in SmPC (section 4.4) and patient information leaflet (section 2).</td>
<td>Not necessary</td>
</tr>
<tr>
<td>Off-label use</td>
<td>The information given in the SmPC is intended to prevent from &quot;off-label use&quot;. The patient is asked to comply with the information given in the patient information leaflet and/or with the advices from the physician or pharmacist.</td>
<td>Not necessary</td>
</tr>
</tbody>
</table>

### Missing information

<table>
<thead>
<tr>
<th>Safety concern</th>
<th>Routine risk minimisation measures</th>
<th>Additional risk minimisation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited information on the use of mupirocin in term and preterm newborn infants under 4 weeks of age is</td>
<td>The use of mupirocin in term and preterm newborn infants under 4 weeks of age is</td>
<td>Not necessary</td>
</tr>
</tbody>
</table>
### IV.7 Discussion on the clinical aspects

With the exception of the therapeutic equivalence study, no new clinical data were submitted and none are required for this type of application.

There are no objections to the approval of this application from a clinical viewpoint.

The grant of a Marketing Authorisation is recommended for this application.

### V User consultation

A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to Mupirocin Infectopharm 20 mg/g Ointment (UK/H/4991/001/DC). The bridging report submitted by the applicant is acceptable.

### VI Overall conclusion, benefit/risk assessment and recommendation

The quality of the product is acceptable, and no new non-clinical or clinical concerns have been identified. Extensive clinical experience with mupirocin is considered to have demonstrated the therapeutic value of the compound. The benefit risk assessment is, therefore, considered to be positive.
Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels
In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The approved labelling for Mupirocin InfectoPharm 20 mg/g ointment is presented below:

| MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS |
| TUBE (5 g) |

| 1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION |
| Mupirocin InfectoPharm 20 mg/g ointment |
| mupirocin |

| 2. METHOD OF ADMINISTRATION |
| For cutaneous use only. |

| 3. EXPIRY DATE |
| Lot/EXP see tube fold |

| 4. BATCH NUMBER |
| Lot/EXP see tube fold |

| 5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT |
| 5 g |

| 6. OTHER |
| PL 15011/0016 |
| INFECTOPHARM |
# PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

**TUBE (15 g)**

---

## 1. NAME OF THE MEDICINAL PRODUCT

Mupirocin InfectoPharm 20 mg/g ointment

mupirocin

---

## 2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 g of ointment contains 20 mg mupirocin.

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## 3. LIST OF EXCIPIENTS

Other ingredients: polyethylene glycol 400 and polyethylene glycol 3350.

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## 4. PHARMACEUTICAL FORM AND CONTENTS

15 g

---

## 5. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use only.
Apply to the affected area as prescribed by your doctor.
Read the package leaflet before use.

---

## 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

---

## 7. OTHER SPECIAL WARNING(S), IF NECESSARY

Avoid contact with the eyes.

---

## 8. EXPIRY DATE

Lot/EXP see tube fold

---

## 9. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Use up within 10 days after first opening.

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## 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF Appropriate

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<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>11.</td>
<td><strong>NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</strong></td>
</tr>
</tbody>
</table>
|   | INFECTOPHARM Arzneimittel und Consilium GmbH  
   | Von-Humboldt-Str. 1  
   | 64646 Heppenheim  
   | Germany |
| 12. | **MARKETING AUTHORISATION NUMBER(S)** |
|   | PL 15011/0016 |
| 13. | **BATCH NUMBER** |
|   | Lot/EXP see tube fold |
| 14. | **GENERAL CLASSIFICATION FOR SUPPLY** |
|   | POM |
| 15. | **INSTRUCTIONS ON USE** |
| 16. | **INFORMATION IN BRAILLE** |
PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON (5 g)

1. NAME OF THE MEDICINAL PRODUCT

Mupirocin InfectoPharm 20 mg/g ointment
mupirocin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 g of ointment contains 20 mg mupirocin.

3. LIST OF EXCIPIENTS

Other ingredients: polyethylene glycol 400 and polyethylene glycol 3350.

4. PHARMACEUTICAL FORM AND CONTENTS

5 g

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use only.
Apply to the affected area as prescribed by your doctor.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Avoid contact with the eyes.

8. EXPIRY DATE

Lot/EXP see tube fold

9. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
After first opening of the tube the contents can be used for up to 10 days.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
INFECTOPHARM Arzneimittel und Consilium GmbH
Von-Humboldt-Str. 1
64646 Heppenheim
Germany

12. MARKETING AUTHORISATION NUMBER(S)

PL 15011/0016

13. BATCH NUMBER

Lot/EXP see tube fold

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

Medical sample – not for sale

15. INSTRUCTIONS ON USE

Optional: pictogram of the pharmaceutical form or the route of administration.

16. INFORMATION IN BRAILLE

Mupirocin 20 mg/g ointment
PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON (15 g)

1. **NAME OF THE MEDICINAL PRODUCT**

Mupirocin InfectoPharm 20 mg/g ointment
mupirocin

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**

1 g of ointment contains 20 mg mupirocin.

3. **LIST OF EXCIPIENTS**

Other ingredients: polyethylene glycol 400 and polyethylene glycol 3350.

4. **PHARMACEUTICAL FORM AND CONTENTS**

15 g

Bundling package

2 x 15 g

5. **METHOD AND ROUTE(S) OF ADMINISTRATION**

For cutaneous use only.
Apply to the affected area as prescribed by your doctor.
Read the package leaflet before use.

6. **SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children.

7. **OTHER SPECIAL WARNING(S), IF NECESSARY**

Avoid contact with the eyes.

8. **EXPIRY DATE**

Lot/EXP see tube fold

9. **SPECIAL STORAGE CONDITIONS**

Do not store above 25 °C.
After first opening of the tube the contents can be used for up to 10 days.

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**
11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

12. MARKETING AUTHORISATION NUMBER(S)

PL 15011/0016

13. BATCH NUMBER

Lot/EXP see tube fold

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Optional: pictogram of the pharmaceutical form or the route of administration

16. INFORMATION IN BRAILLE

Mupirocin 20 mg/g ointment
Table of content of the PAR update for MRP and DCP

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitments)

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