SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Name of the Medicinal Product

BOTIGO

(Mupirocin Ointment USP 2% w/w)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Mupirocin USP	2 % w/w
In a non-greasy base	q.s.

3. PHARMACEUTICAL FORM

Off White coloured smooth cream.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Mupirocin is indicated in adults and children.

Mupirocin 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 Ointment is used for skin infections, e.g. impetigo, folliculitis, furunculosis.

4.2. Posology and method of administration

Posology:

Adults (including elderly) and Paediatric population:

Mupirocin Ointment 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 if desired.

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 ointment.

4.3. Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1

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

4.4. Special warnings and special precautions for use

Should a possible sensitization reaction or severe local irritation occur with the use of Mupirocin 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 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.

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.

Mupirocin Ointment is not suitable for:

- ophthalmic use;
- intranasal use (in neonates or infants);
- use in conjunction with cannulae;
- 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.

4.5. Interactions with other Drug products and other forms of interaction

No interaction studies have been performed

4.6 Pregnancy and lactation

Pregnancy:

Reproduction studies on mupirocin in animals have revealed no evidence of harm to the foetus (see section 5.3). As there is no clinical experience on its use during pregnancy, Mupirocin Ointment 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 (see section 5.3).

4.7 Effects on ability to drive and use machines

Mupirocin 2% w/w Ointment has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (1/10), common (1/100 to <1/10), uncommon (1/1,000 to <1/100), rare (1/10,000 to <1/1,000), very rare(<1/10,000), including isolated reports.

Common and uncommon adverse reactions were determined from pooled safety data from a clinical trial population of1573 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.

System organ class	Frequency	Undesirable effects
Immune system disorders	Very rare	Systemic allergic reactions including anaphylaxis, generalised rash, urticaria and angioedema have been reported with Mupirocin Ointment.
Skin and subcutaneous tissue disorders	Common Uncommon	Burning localised to the area of application Itching, erythema, stinging and dryness localised to the area of application. Cutaneous sensitisation reactions to mupirocin or the ointment base.

4.9 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: Antibiotics and chemotherapeutics for topical use, ATC code: D06AX09

Mechanism of action

Mupirocin is a novel antibiotic produced through fermentation by Pseudomonas fluorescens. Mupirocin inhibits isoleucyltransfer-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.

Commonly susceptible species
*Staphylococcus aureus**
Streptococcus pyogenes*
Streptococcus spp. (β -haemolytic, other than S. pyogenes)
Species for which acquired resistance may be a problem
Staphylococcus spp., coagulase negative
Inherently resistant organisms
Corynebacterium spp.
Micrococcus spp.

* Activity has been satisfactorily demonstrated in clinical studies

5.2 Pharmacokinetic Properties

After topical application of Mupirocin Ointment, mupirocin is only very minimally absorbed systemically and that which is absorbed is rapidly metabolised to the antimicrobially inactive metabolite, monic acid. Penetration of mupirocin into the deeper epidermal and dermal layers of the skin is enhanced in traumatised skin and under occlusive dressings.

Elderly:

No restrictions unless there is evidence of moderate or severe renal impairment (see section 4.4).

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

Polyethylene glycol 400

Polyethylene glycol 4000

Glyceryl Monosterate

Propylene Glycol

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 Months

6.4 Special precautions for storage

Do not store above 30ºC, Protect from light.

6.5. Nature and contents of container

1 x 15 gm lame tube

6.6. Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Base Medico Pvt. Ltd.,
Survey No. 570, Village Tundav, Tal. Savli,
Dist. Vadodara - 391775, Gujarat, India.

8. DRUG PRODUCT MANUFACTURER

Not Applicable

9. NAFDAC REGISTRATION NUMBER(S)
