SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

BACODERM 2 % Pomade

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each tube (15 g) contains 2 % w/w mupirocin.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment ; White, semi-transparent ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BACODERM is used for skin infections, impetigo, folliculitis, furunculosis.

4.2 Posology and method of administration

Posology

Dosage

A thin layer of BACODERM should be applied to the affected area two or three times a day for up to 10 days, depending on the response.

Additional data concerning special populations:

Renal/Hepatic impairment: See for hepatic impairment (*See:* Posology and method of administration). Also See for renal impairment (*See:* Special warnings and precautions for use)

Pediatric population: *See:* Special warnings and precautions for use

Geriatric population: *See:* Special warnings and precautions for use

Method of administration

The treated area may be covered by a dressing.

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

Drill tube mouth by turning upside down before first using.

If product is present at the end of treatment, should be discarded/destroyed.

4.3 Contraindications

BACODERM should not be given to patients with a history of hypersensitivity to mupirocin and any of its excipients.

4.4 Special warnings and precautions for use

Avoid contact with the eyes when BACODERM is used on face.
As with all topical preparations, precaution should be taken to avoid contact with the eyes.

Should a possible sensitisation reaction or severe local irritation occur with the use of BACODERM, 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.
Elderly patients: No restrictions unless the condition being treated could lead to absorption of polyethylene glycol and there is evidence of moderate or severe renal impairment.

BACODERM Pomade is not suitable for;

- Ophthalmic use
- Intranasal use (in neonates or infants)
- Use in conjunction with cannula
- 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.

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, BACODERM Pomade 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.

4.5 Interaction with other medicinal products and other forms of interaction

No drug interactions are defined.

Additional data concerning special populations:

No data

Pediatric population:

No data

4.6 Fertility, pregnancy and lactation

Pregnancy category: B

Women of childbearing potential / Contraception in females

As there is no clinical experience on its use in women of childbearing potential, BACODERM should only be used in women of childbearing potential when the potential benefits outweigh the possible risks of treatment.

Pregnancy

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

Lactation

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

Fertility

No data

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

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

Very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000), unknown (Can not be estimated from the available data.)

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.

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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D06AX09

Pharmacotherapeutic group: Antibiotics (Dermatologicals)

Mupirocin is a novel antibiotic produced through fermentation by *Pseudomonas fluorescens*. Mupirocin inhibits isoleucyl transfer-RNA syntheses, thereby arresting bacterial protein synthesis. Due to this particular mechanism of mupirocin, other classes of antibacterial agents in vitro cross resistance. Mupirocin is used in the description of one selected as very low risk of bacterial resistance.

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

Mupirocin *Staphylococcus aureus* (including methicillin-resistant strains), *S. and beta-hemolytic Streptococcus epidermidis* exhibit activity in vivo against type topical antibacterial agent.

The following bacteria is effected as in-vitro.

Aerobic Gram-positive:

• *Staphylococcus aureus* (beta-lactamase-producing species and including methicillin-resistant strains)

• *Staphylococcus epidermidis* (beta-lactamase-producing species and including methicillin-resistant strains

• Other coagulase negative staphylococci (species including methicillin-resistant)

• *Streptococcus species*

Aerobic Gram-negative:

Mupirocin effects against to some gram-negative organisms causing skin infection (although not nasal colonization):

• *Haemophilus influenzae*

• *Neisseria gonorrhoeae*

• *Neisseria meningitidis*

• *Moraxella catarrhalis*

• *Pasteurella multocida*

• *Proteus mirabilis*

• *Proteus vulgaris*

• *Enterobacter cloacae*

• *Enterobacter aerogenes*

• *Citrobacter freundii*

• *Bordetella pertussis*

Mupirocin value range

Equivalent to S 4 microgram/ml or less; equivalent to R 8 microgram/ml or more.

Sensitive bacteria

*Staphylococcus aureus*1

*Staphylococcus epidermidis*1

Coagulase-negative *staphylococci*1

Streptococcus speciecis 1

Haemophilus influenzae

Neisseria gonorrhoeae

Neisseria meningitidis

Moraxella catarrhalis

Pasteurella multocida.

1Approved indications for sensitive bacteria isolated in clinical efficacy has been proven.

Resistant ratio: 0% - 23%

Non-susceptible bacteria

Corynebacterium species

Enterobacteriaceae

Gram negative non-fermenting stick figures

Micrococcus species

Anaerobs

Mechanism of resistance

Low-level resistance in staphylococci (MICs 8-256 microgram/mL) is thought to result from the target isoleucyl tRNA synthetase enzyme. High-level resistance in staphylococci (Equal or more than MICs 512 microgram/ml) 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.

5.2 Pharmacokinetic properties

General properties

Absorption: Systemic absorption of mupirocin through intact human skin is low.

Distribution: No data.

Biotransformation: Mupirocin is suitable only for topical application. Penetration of mupirocin into the deeper epidermal and dermal layers of the skin is enhanced in traumatised skin and under occlusive dressings.

Excretion: 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

Carcinogenesis: No carcinogenicity studies have been conducted with mupirocin.

Genotoxicity: Mupirocin has not been found to be mutagenic in *Salmonella typhimurium* or *Escherichia coli* (AMES analysis). In Yahagi analysis, small increases were observed in *Salmonella typhimurium* TA98 at highly cytotoxic concentrations. In *in vitro* mammalian gene mutation analysis (MLA), no increase was observed in mutation frequency in the absence of metabolic activation. In the presence of metabolic activation, small increases were observed in mutation frequency at highly cytotoxic concentrations. However, any effect was not observed in yeast cell analyses for gene conversion/mutation, *in vitro* human lymphocyte analysis or *in vitro* unprogrammed DNA synthesis (UDS) analysis. Furthermore, *in vivo* mouse micronucleus analysis (chromosome damage) and a rat Comet analysis (DNA strand breakage) were negative, indicating the small increases observed at *in vitro* highly cytotoxic concentrations do not show ability as *in vivo*.

Reproductive Toxicology: Mupirocin administered subcutaneously to 10-week-old male rats and 15-day-old female rats before mating, until 20 days post mating at doses up to 100 mg/kg/day had no effect on fertility.
In embryo-fetal development studies were conducted in rats, there was no evidence of developmental toxicity at subcutaneous doses up to 375 mg/kg/day.

In an embryo-fetal development study that was conducted in rabbits at subcutaneous doses up to 160 mg/kg/day, high dose maternal toxicity (impaired weight gain and severe injection site irritation) was resulted with abortion or poor litter performance. However, there was no evidence of developmental toxicity in fetuses of rabbits was protected pregnancy to term.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 400
Macrogol 3350

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30 ºC at room temperature.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

15 g aluminium tubes with plastic screw cap with a patient information leaflet in a carton box.

6.6 Special precautions for disposal <and other handling>

The unused products or waste materials should be destroyed in accordance with "The Regulation Regarding the control of Medical Wastes Published" and "The Regulation Regarding the Control of Packages and Package Wastes Published".

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

Certificate No: 05806/07754/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Mar 23, 2021

10. DATE OF REVISION OF THE TEXT

September 2023