SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

Brand name: BACTROX

Product name: Mupirocin Ointment

Strength: 20mg

Pharmaceutical: Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative Declaration, The active substance should be declared by its recommended INN. Accompanied by itssalt or hydrate form if relevant

Mupirocin

Quantitative Declaration, The quantity of the active substance must be expressed per dosage unit.

Each gram contains Mupirocin 20mg

3. PHARMACEUTICAL FORM

A white or almost white ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Mupirocin Ointment is indicated for the treatment of acute primary bacterial skin infections e.g. impetigo and folliculitis due to organisms sensitive to the active ingredient..

4.2 Posology/Dosage and method of administration

Mupirocin Ointment should be applied to the affected area up to three times a day for up to 10 days, depending on the response. Dosage should not exceed ten days. The area may be covered with a dressing or occluded if desired.

Administration:

Cutaneous use.

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.

4.3 Contraindication

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

In the rare event of a possible sensitisation reaction or severe local irritation occurring with the use of the product, treatment should be discontinued, the product should be wiped off and appropriate alternative therapy for the infection 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

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.

Mupirocin ointment is not suitable for:

- ophthalmic use
- intranasal use
- use in conjunction with cannulae
- at the site of central venous cannulation.

For intranasal use, a separate presentation, Mupirocin nasal ointment, is available.

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, 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.

4.5 Interaction with other drug products and other forms of interaction

None reported.

4.6 Fertility, pregnancy and lactation

Pregnancy

Adequate human data on use during pregnancy are not available. Studies in animals do not indicate reproductive toxicity.

Lactation

Adequate human and animal data on use during lactation are not available.

Fertility

There are no data on the effects of mupirocin on human fertility. Studies in rats showed no effects on fertility.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Adverse events thought to be possibly or probably occurred in less than 1% of subjects were: abdominal pain, burning at application site, cellulitis, dermatitis, dizziness, pruritus, secondary wound infection, and ulcerative stomatitis.

The incidence of adverse events thought to be possibly occurred more than 1% was as follows: nausea (4.9%), headache, and burning at application site (3.6% each), pruritus (2.4%), bleeding secondary to eczema, pain secondary to eczema, hives, dry skin, and rash.

Systemic allergic reactions, including anaphylaxis, urticaria, angioedema, and generalized rash have been reported in patients treated with Mupirocin.

4.9 Overdose

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Mode 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.

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.

5.3 Preclinical safety data

Carcinogenesis/Mutagenesis

Carcinogenesis

Carcinogenicity studies with mupirocin have not been conducted.

Genotoxicity

Mupirocin was not mutagenic in Salmonella typhimurium or Escherichia coli (Ames assay). In a Yahagi assay, small increases in Salmonella typhimurium TA98 were observed at highly cytotoxic concentrations. In an in vitro mammalian gene mutation assay (MLA), no increase in mutation frequency was observed in the absence of metabolic activation. In the presence of metabolic activation, small increases in mutation frequency were observed at highly cytotoxic concentrations. However, no effects were observed in, yeast cell assays for gene conversion/mutation, an in vitro human lymphocyte assay or in an in vitro unscheduled DNA synthesis (UDS) assay. Furthermore, an in vivo mouse micronucleus assay (chromosome damage) and a rat Comet assay (DNA strand breakage) were negative, indicating the small increases observed at highly cytotoxic concentrations in vitro do not translate to the in vivo situation.

Reproductive Toxicology

Fertility

Mupirocin administered subcutaneously to male rats 10 weeks prior to mating and to female rats 15 days prior to mating until 20 days post coitum at doses up to 100 mg/kg/day had no effect on fertility.

Pregnancy

In embryo-foetal development studies in rats there was no evidence of developmental toxicity at subcutaneous doses up to 375 mg/kg/day.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene Glycol 400, Polyethylene Glycol 3350

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30°C in dry place away from sunlight.

Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

Collapsible aluminum tube having a screw threaded neck finish sealed with an aluminum membrane. Each tube is supplied with a white polyethylene screw cap which has a piercing tip to puncture open the aluminum membrane on the neck.

Pack size:5g, 15g

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 F PRODUCT REGISTRATION

Applicant: AKSO PHARMACEUTICAL NIGERIA LIMITED..

Adress: No. 320, Odusami Street, off Wempco Road, Ogba , Lagos Nigeria

E-mail: 506798052@qq.com

Contact person : Brian Fu

Tel: 09118269061

8. DRUG PRODUCT MANUFACTURER

Manufacturer name: FRONT PHARMACEUTICAL PLC

Physical address: No.369 Baocheng Road, Xuancheng Economic and Technical Development Zone, Anhui, China

Tel: 86-0563-2625199

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E-mail: export@frontpharm.com

9. NAFDAC REGISTRATION NUMBER(S)