NEW ZEALAND DATA SHEET

1. FOBAN TOPICAL CREAM

Fusidic acid 2% cream & sodium fusidate 2% ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Foban cream contains fusidic acid 20mg each gram and Foban ointment contains sodium fusidate 20mg each gram.

Excipients with known effect:

Foban cream: Liquid paraffin, white soft paraffin, cetomacogol 1000, cetostearyl alcohol, propylene glycol, methyl paraben, propyl paraben and water

Foban ointment: Liquid paraffin, white soft paraffin

3. PHARMACEUTICAL FORM

Topical cream.

Foban cream is a smooth and white cream and Foban ointment is a colourless ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Indicated either alone or in combination with systemic therapy, in the treatment of primary and secondary skin infections caused by sensitive strains of Staphylococcus aureus, Streptococcus spp and Corynebacterium minutissimum. Primary skin infections that may be expected to respond to treatment with fusidic acid applied topically include: impetigo contagiosa, superficial folliculitis, sycosis barbae, paronychia and erythrasma; also such secondary skin infections as infected eczematoid dermatitis, infected contact dermatitis and infected cuts / abrasions.

4.2 Dose and method of administration

Adults and Children:

Uncovered lesions - apply gently three or four times daily.

Covered lesions - less frequent applications may be adequate.

4.3 Contraindications

Infection caused by non-susceptible organisms, in particular, Pseudomonas aeruginosa.

Foban Cream and Ointment is contraindicated in patients with hypersensitivity to fusidic acid and its salts.

4.4 Special warnings and precautions for use

Bacterial resistance has been reported to occur with the use of fusidic acid applied topically. As with all topical antibiotics, extended or recurrent application may increase the risk of contact sensitisation and the development of antibiotic resistance.

The sodium salt of fusidic acid has been shown to cause conjunctival irritation. The ointment should not be used near the eye.

Fusidic acid does not appear to cause conjunctival irritation in experimental animals. Caution should be exercised, however, when Foban Cream is used near the eyes.

4.5 Interaction with other medicines and other forms of interaction

Not applicable.

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Animal studies and many years of clinical experience have suggested that fusidic acid is devoid of teratogenic effect. There is evidence to suggest that when given systemically, fusidic acid can penetrate the placental barrier. The use of topical Foban in pregnancy requires that the potential benefits be weighed against the possible hazards to the foetus.

Safety in nursing mothers has not been established. When fusidic acid (as the sodium salt) has been given systemically, levels have been detected in breast milk, but with topical use the possible amount of drug present is unlikely to affect the infant.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Hypersensitivity reactions to the active ingredient in the form of skin rashes; mild stinging and irritation on application have been reported rarely.

4.9 Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Fusidic acid is a potent antibacterial agent. Fusidic acid and its salts show fat and water solubility and strong surface activity and exhibit unusual ability to penetrate intact skin. Concentrations of 0.03 - 0.12 mcg fusidic acid per ml inhibit nearly all strains of Staphylococcus aureus. Topical application of fusidic acid is also effective against streptococci, corynebacteria, neisseria and certain clostridia.

5.2 Pharmacokinetic properties

In Vitro studies show that fusidic acid can penetrate intact human skin. The degree of penetration depends on factors such as the duration of exposure to fusidic acid and the condition of the skin. Fusidic acid is excreted mainly in the bile with little excreted in the urine.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Other excipient:

Cetomacrogol 1000, cetostearyl alcohol, liquid paraffin, propylene glycol, purified water, white soft paraffin.

Other excipient, preservative:

Methyl hydroxybenzoate, propyl hydroxybenzoate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years from date of manufacture.

6.4 Special precautions for storage

Store at or below 30ºC.

6.5 Nature and contents of container

Aluminium tubes of 15 gram.

6.6 Special precautions for disposal

No special requirements.

7. MEDICINE SCHEDULE

Prescription medicine.

8. DATE OF FIRST APPROVAL

27 January 2005

9. DATE OF REVISION OF THE TEXT

February 2019

SUMMARY TABLE OF CHANGES

Date	Section(s) Changed	Change (s)
February 2019	All	Reformat consistent with new Medsafe Data Sheet Template.