PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

STAFUBAK OINTMENT 20 mg/g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 20 mg sodium fusidate.

Excipients with known effect:

Contains alcohol (cetyl alcohol): 0,4 % *m/m*

Lanolin (wool fat).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment for topical administration.

Off-white ointment free from foreign particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

STAFUBAK OINTMENT is indicated either alone or in combination with systemic therapy, in the treatment of skin infections caused by Gram-positive organisms, particularly the *Staphylococcus*, e.g. abscesses, boils, carbuncles, impetigo, eczema, varicose ulcers, skin grafts, wounds, burns.

4.2 Posology and method of administration

Uncovered lesions: Apply gently, three or four times daily.

Covered lesions: Less frequent applications may be adequate.

4.3 Contraindications

- hypersensitivity to sodium fusidate or to any of the excipients listed in section 6.1;
- infection caused by non-susceptible organisms, in particular *Pseudomonas aeruginosa*.

4.4 Special warnings and precautions for use

The sodium salt of fusidic acid has been known to cause conjunctival irritation. STAFUBAK OINTMENT should not be used in or near the eyes.

Bacterial resistance among *staphylococcus aureus* has been reported to occur with the use of topical STAFUBAK OINTMENT. As with all antibiotics, extended or recurrent use may increase the risk of developing antibiotic resistance.

Extended or recurrent use may increase the risk of developing contact sensitisation.

STAFUBAK OINTMENT contains cetyl alcohol and lanolin (wool fat). These excipients may cause local skin reactions (e.g. contact dermatitis).

When STAFUBAK OINTMENT ointment is used on the face; care should be taken to avoid the eyes as the excipients in the ointment may cause conjunctival irritation.

Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with STAFUBAK OINTMENT burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed. Interactions with systemically administered medicines are considered minimal as the systemic absorption of topical STAFUBAK OINTMENT is negligible.

4.6 Fertility, pregnancy and lactation

The safety of this preparation in pregnancy and lactation has not been established.

Pregnancy

No effects during pregnancy are anticipated, since systemic exposure to topically applied fusidic acid/sodium fusidate is negligible.

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of topically applied fusidic acid/sodium fusidate to the breastfeeding woman is negligible. It is recommended to avoid applying topical STAFUBAK OINTMENT on the breast.

Fertility

There are no clinical studies with topical STAFUBAK OINTMENT regarding fertility. No effects in women of childbearing potential are anticipated, since systemic exposure following topically applied fusidic acid/sodium fusidate is negligible.

4.7 Effects on ability to drive and use machines

STAFUBAK OINTMENT administered topically has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders

Less frequent: hypersensitivity

Eye disorders

Less frequent: conjunctivitis

Skin and subcutaneous tissue disorders

Less frequent: dermatitis (including contact dermatitis, eczema),rash*, pruritus, erythema, angioedema, urticaria, blister

*Various types of rash reactions such as erythematous, pustular, vesicular, maculo-papular and papular have been reported. Generalised rash has also occurred.

General disorders and administrative site conditions

Less frequent: application site pain (including skin burning sensation), application site irritation.

Paediatric population

Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of STAFUBAK OINTMENT is important. It allows continued monitoring of the benefit/risk balance of STAFUBAK OINTMENT. Health care providers are asked to report any suspected adverse reactions via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

None known.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 20.1.6. Topical Antibiotics

Pharmacotherapeutic group: Other antibiotics for topical use

ATC code: D06AX01

Fusidic acid is a potent topical 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 microgram 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.

Resistant organisms

Pseudomonas auruginosa.

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

No information of relevence available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetyl alcohol

Liquid paraffin

White soft paraffin

Wool fat

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

Store at or below 25 °C.

6.4 Special precautions for storage

Keep the container tightly closed.

6.5 Nature and contents of container

Aluminium tubes with a white HDPE cap containing 15 g ointment.

6.6 Special precautions for disposal and other handling

None.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Activo Health (Pty) Ltd

Block B, Arena Office Park

272 West Avenue, Centurion

0157

8. REGISTRATION NUMBER

48/20.1.6/0947

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6 July 2021

10. DATE OF REVISION OF THE TEXT

15 July 2022