PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

STAFUBAK CREAM 20 mg/g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 20 mg fusidic acid.

Excipients with known effect:

Butylated hydroxyanisole

Contains alcohol (cetyl alcohol): 11,10 % *m/m*

Contains preservative: potassium sorbate 0,27 % *m/m*.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream for topical administration.

White, smooth, homogeneous cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

STAFUBAK CREAM is indicated either alone or in combination with systemic therapy, in the treatment of skin infections caused by Staphylococci.

4.2 Posology and method of administration

Posology

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

Covered lesions: Less frequent applications may be adequate.

Method of administration

Cutaneous use.

4.3 Contraindications

- hypersensitivity to fusidic acid 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

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

STAFUBAK CREAM contains butylated hydroxyanisole, cetyl alcohol and potassium sorbate. These excipients may cause local skin reactions (e.g. contact dermatitis). Butylated hydroxyanisole may also cause irritation to the eyes and mucous membranes. STAFUBAK CREAM should therefore be used with care when applied in the proximity of the eyes.
Caution should be exercised when using STAFUBAK CREAM near the eyes.

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 CREAM 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 CREAM is negligible.

4.6 Fertility, pregnancy and lactation

Safety 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. Topical STAFUBAK CREAM can be used during breastfeeding but it is recommended to avoid applying topical STAFUBAK CREAM on the breast.

Fertility:

There are no clinical studies with topical STAFUBAK CREAM 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 CREAM 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 reactions

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 CREAM is important. It allows continued monitoring of the benefit/risk balance of STAFUBAK CREAM. 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

Overdose is unlikely to occur.

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 antibacterial medicine. 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.

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

Butylated hydroxyanisole (E320)

Cetyl alcohol

Glycerol

Hydrochloric acid (pH adjuster)

Liquid paraffin

Potassium sorbate (E202)

Polysorbate 60

Purified water

White soft paraffin.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep the container tightly closed.

6.5 Nature and contents of container

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

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

48/20.1.6/0946

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6 July 2021

10. DATE OF REVISION OF THE TEXT

15 July 2022