PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

STAFUBAK CREAM 20 mg/g

Fusidic acid

Contains butylated hydroxianisole

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

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

Read all of this leaflet carefully before you start taking STAFUBAK CREAM

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- STAFUBAK CREAM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What STAFUBAK CREAM is and what it is used for
2. What you need to know before you use STAFUBAK CREAM
3. How to use STAFUBAK CREAM
4. Possible side effects
5. How to store STAFUBAK CREAM
6. Contents of the pack and other information

1. What STAFUBAK CREAM is and what it is used for

STAFUBAK CREAM contains the active ingredient fusidic acid.

STAFUBAK CREAM is used to treat conditions where the skin is infected by germs (bacteria).

2. What you need to know before you use STAFUBAK CREAM

Do not use STAFUBAK CREAM

If you are hypersensitive (allergic) to fusidic acid or to any of the other ingredients of STAFUBAK CREAM listed in section 6 of this leaflet.

Warnings and precautions

Take special care with STAFUBAK CREAM if you or a child in your care:

- are going to use STAFUBAK CREAM near your eyes;
- use STAFUBAK CREAM over a long time or in large amounts it may make the chance of getting any side effects higher. Your skin may also get more sensitive to STAFUBAK CREAM.

Do not 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.

Other medicines and STAFUBAK CREAM

Always tell your health care provider if you or a child in your care are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using STAFUBAK CREAM.

Safety of STAFUBAK CREAM during pregnancy and breastfeeding has not been established.

Avoid applying STAFUBAK CREAM on your breasts while breastfeeding.

Driving and using machines

STAFUBAK CREAM will have very little or no effect on your ability to drive or use machines.

STAFUBAK CREAM contains butylated hydroxyanisole, cetyl alcohol and potassium sorbate

These ingredients may cause an itchy rash and redness on the applied area on your skin. It may also cause irritation to the eyes and mucous membranes (such as lips or genital area).

3. How to use STAFUBAK CREAM

Do not share medicines prescribed for you or a child in your care with any other person.

Always use STAFUBAK CREAM exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

STAFUBAK CREAM is only for use on your skin or the skin of a child. Do not swallow or put STAFUBAK CREAM inside your body.

Usually, you should apply STAFUBAK CREAM three or four times each day.

If you have been told to cover the skin with any dressings or bandages you may not need to use STAFUBAK CREAM so often. A nappy on a baby may act as a dressing.

How to put on STAFUBAK CREAM:

1. Remove the cap. Check that the seal is not broken before you first use STAFUBAK CREAM.
2. Push the spike in the cap through the seal on the tube.
3. Always wash your hands before using STAFUBAK CREAM.
4. Rub STAFUBAK CREAM gently on the skin. If you use STAFUBAK CREAM on your face be careful to avoid your eyes.

5. Unless you are using the cream to treat your hands, always wash your hands after using STAFUBAK CREAM.
6. If you accidentally get any STAFUBAK CREAM in your eye, wash it out with cold water straight away. Then bathe your eye with eyewash if possible. Your eye may sting. If you start to have any problems with your sight or your eye is sore, contact your doctor immediately.

Your doctor will tell you how long your treatment with STAFUBAK CREAM will last.

If you have the impression that the effect of STAFUBAK CREAM is too strong or too weak, tell your doctor or pharmacist.

If you use more STAFUBAK CREAM than you should

If you accidentally apply too much STAFUBAK CREAM or have swallowed a small quantity of the cream, it is unlikely to cause any harm.

However, if a large quantity of STAFUBAK CREAM is accidently swallowed; consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. You or a child in your care may may require medical attention. Take the medicine pack with you.

If you forget to use STAFUBAK CREAM

If you forget to use STAFUBAK CREAM, use it as soon as you remember.

Apply STAFUBAK CREAM at the usual time from then on.

4. Possible side effects

STAFUBAK CREAM can have side effects.

Not all side effects reported for STAFUBAK CREAM are included in this leaflet. Should your or a child in your care’s general health worsen or if you experience any untoward effects while taking STAFUBAK CREAM, please consult your health care provider for advice.

If any of the following happens, stop using STAFUBAK CREAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

These are all very serious side effects. If you or a child in your care have them, you may have had a serious reaction to STAFUBAK CREAM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- itchy or dry skin, blisters on your skin;
- itching and redness of your eyes, also called “pink eye”;
- pain or irritation at the site of application, including burning, stinging and skin redness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of STAFUBAK CREAM.

5. How to store STAFUBAK CREAM

- Store at or below 25 °C.
- Keep the container tightly closed.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What STAFUBAK CREAM contains

The active substance in STAFUBAK CREAM is fusidic acid.

Each gram contains 20 mg fusidic acid.

The other ingredients are:

Butylated hydroxyanisole (E320)

Cetyl alcohol

Glycerol

Hydrochloric acid (pH adjuster)

Liquid paraffin

Potassium sorbate (E202)

Polysorbate 60

Purified water

White soft paraffin.

What STAFUBAK CREAM looks like and contents of the pack

White, smooth, homogeneous cream.

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

Holder of certificate of registration

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0157

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