

FUSIDIC ACID

FUSADOC

20 mg/g (2% w/w) Topical Cream
Antibacterial

PRODUCT DESCRIPTION

Fusidic acid cream is off white, thick, soft mass cream.

FORMULATION

Each gram contains:

Fusidic Acid BP (2%w/w).....20mg

WHAT IS IN THE MEDICINE?

Fusidic acid cream contains Fusidic acid as an active ingredient. It is a type of antibiotic.
Fusidic acid cream works by killing germs (bacteria) that cause infections.

WHAT IS THIS MEDICINE USED FOR?

Fusidic acid cream is indicated either as a single or in combination to systemic therapy for the treatment of primary and secondary skin infections caused by sensitive strain of staphylococcus species 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/abrasion.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

The duration of the treatment will be decided by your doctor. Treatment is usually 1 to 2 weeks, although it may be longer. This depends on the type of infection and the result of the treatment. Take special care if you use the cream for a long time or in large amounts, because then there is a higher chance of getting side effects. Therefore, always follow the advice of your doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

If you are allergic to fusidic acid or any of the other ingredients of this medicine.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

Take special care if you are going to use this medicine near your eyes or the eyes of a child.
If you use the cream over a long time or in large amounts it may make the chance of getting any side effects higher. Also your skin may get more sensitive to this medicine.

UNDESIRABLE EFFECTS OF THIS MEDICINE

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most frequently reported side effects are various skin reactions and in particular application site reactions. The frequency of occurrence of side effects is as follows:

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Uncommon side effects: Itching, Rash, Eczema, Skin sensitivity reactions (contact dermatitis), Irritation at site of application (including pain, burning, irritation, stinging and skin redness)

Rare: Conjunctivitis, Hives, Swelling of the skin, Blister

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.
Some medicines may be affected by Fusidic acid cream or may affect how well Fusidic acid cream works. You may need different amounts of your medicines, or you may need to take different medicines.
Fusidic acid cream applied on the skin will not generally interfere with other antibacterial treatment, for example antibiotic tablets or injections.
Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

WHAT SHOULD YOU DO IF YOU HAVE TAKEN MORE THAN RECOMMENDED DOSAGE?

If you apply too much or accidentally swallow Fusidic acid cream, it is unlikely to cause any harm. However, if you notice any effect or are worried, contact your doctor or pharmacist. You should contact the doctor if Fusidic acid cream is accidentally swallowed by an infant.

SIGNS AND SYMPTOMS OF OVERDOSE

Overdose is unlikely.

Unless hypersensitivity to fusidic acid or any of the excipients exist, accidental ingestion of Fusidic acid cream is unlikely to cause any harm. The total quantity of fusidic acid will usually not exceed the approved total daily oral dose of fusidic acid containing products except in children aged less than 1 year and weighing ≤ 10 kg.

Although in this instance a child of this particular age group is unlikely to ingest a whole tube of Fusidic acid 20mg/g cream, The concentration of the excipients is too low to constitute a safety risk.

HOW SHOULD YOU KEEP THIS MEDICINE?

KEEP OUT OF THE REACH OF CHILDREN.

Do not use this medicine after the expiry date which is stated on the carton or the tube. The expiry date refers to the last day of that month.

Store at temperatures not exceeding 30°C.

Discard the tube after 4 weeks of first opening the tube even if there is still some cream left in it

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Reporting of Suspected Adverse Reactions: To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph Patients are advise to seek immediate medical attention, at first sign/s of adverse reactions.

AVAILABILITY

Laminated Tube x 15 g (Box of 1's)

FDA Reg. No.: DRP-11701

Date of First/Renewal of Authorization: 18 April 2022

Date of Revision of Package Insert: 25 January 2023

Rhyburg

Manufactured by:

Rhyburg Pharmaceuticals Limited

C-2 & 3, Sara Industrial Estate Limited,
Selaqui, Dehradun, Uttarakhand, India

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Imported & Distributed by:

SAHAR INTERNATIONAL TRADING INC.

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DRP-11701-01