

Fusiderm®

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fusiderm Cream and Ointment Fusidic acid and Sodium fusidate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT FUSIDERM IS AND WHAT IT IS USED FOR
2. BEFORE YOU USE FUSIDERM
3. HOW TO USE FUSIDERM
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE FUSIDERM
6. FURTHER INFORMATION

1. WHAT FUSIDERM IS AND WHAT IT IS USED FOR

Fusiderm contains fusidic acid. It is a type of antibiotic. Fusiderm works by killing germs (bacteria) that cause infections.

Fusiderm is used to treat conditions where the skin is infected by germs (bacteria), such as:

- Impetigo (a weeping, crusty and swollen patch of skin)
- Infected dermatitis (inflammation of the skin) and spots
- Infected cuts and grazes

2. BEFORE YOU USE FUSIDERM

Do not use Fusiderm

- If you are allergic (hypersensitive) to fusidic acid or sodium fusidate.
- If you are allergic (hypersensitive) to any of the other ingredients in your medicine. You can find a list of these ingredients in section 6 of this leaflet.

Take special care with Fusiderm

- Take special care if you are going to use this medicine near your eyes or the eyes of a child.
- If you use Fusiderm 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines. This includes any medicines which you have bought without a prescription.

Pregnancy and breast-feeding

Please ask your doctor or pharmacist for advice before using Fusiderm:

- If you are pregnant, or think you are pregnant. You must not use your medicine for a long time or in large amounts. You must ask your doctor for advice.
- If you are breast-feeding.

Tell your doctor if you become pregnant while using this medicine.

Driving and using machines

Usually your medicine will have very little effect on your ability to drive or use machines. Check with your doctor if you feel any side effect that may stop you from driving or using machines.

3. HOW TO USE FUSIDERM

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

How to put on Fusiderm

This medicine is only for using on your skin or the skin of a child. Do not swallow it. Do not put it inside your body.

Remove the cap. Check the seal is not broken before you first use the cream or ointment. Then push the spike in the cap through the seal on the tube.

Always wash your hands before using Fusiderm. Rub the medicine gently on the skin. If you use it on your face be careful to avoid your eyes.

Unless you are using Fusiderm to treat your hands, always wash your hands after using Fusiderm.

If you accidentally get any medicine in your eye, wash it out with cold water straight away. If you start to have any problems with your sight or your eye is sore, contact your doctor immediately.

How much Fusiderm to use

Your doctor will tell you how much Fusiderm to use.

Usually, you should use this medicine 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 the medicine so often. A nappy on a baby may act as a dressing. Follow the advice of your doctor.

What to do if you use more Fusiderm than you should

If you accidentally apply too much or a small quantity of Fusiderm is accidentally swallowed, it is unlikely to cause any harm. If a larger quantity of Fusiderm is accidentally swallowed or you are worried contact your doctor or pharmacist.

If you forget to use Fusiderm

If you forget to use this medicine, use it as soon as you remember. Then next use this medicine at the usual time.

If you have any further questions about using this medicine, please ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Fusiderm can cause side effects, although not everybody gets them. Important side effects to look out for:

You must get urgent medical help if you have any of the following symptoms. You may be having an allergic reaction:

- You have difficulty breathing
- Your face or throat swell
- Your skin develops a severe rash

Other possible side effects:

Uncommon side effects (probably affect less than 1 in 100 people)

- Irritation at site of application (including pain, burning, stinging and skin redness)
- Itching
- Rash

Rare side effects (probably affect less than 1 in 1,000 people)

- Conjunctivitis

Side effects where the number of people affected is not known:

- Hives
- Eczema

If any of the side effects become serious or you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

5. HOW TO STORE FUSIDERM

- Keep out of the reach and the sight of children.
- Do not use Fusiderm after the expiry date on the carton. The expiry date is the last day of that month.
- Store below 30°C.

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need any more. If you do this you will help protect the environment.

6. FURTHER INFORMATION

What Fusiderm contains:

The active ingredient is:

Fusidic acid or sodium fusidate.

Fusiderm cream contains 20 mg/gm fusidic Acid.

Fusiderm ointment contains 20 mg/gm sodium fusidate.

The other ingredients are:

Cetomacrogol Emulsifying Wax, Chlorocresol, Liquid Paraffin, Macrogol 300, White Soft Paraffin and Purified Water.

What Fusiderm looks like and contents of the pack:

Fusiderm cream is white homogenous cream.

Fusiderm ointment is a smooth, uniform, greasy translucent ointment.

Fusiderm pack contains 15 gm or 30 gm in an aluminium Tube.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

SPIMACO

Al-Qassim Pharmaceutical Plant

Saudi Pharmaceutical Industries & Medical Appliances Corporation

Saudi Arabia

This leaflet was approved in August 2016.

Version: 1.

Fusiderm is a trade mark
34F1713

To report any side effect(s):

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- o Fax: +966-11-205-7662
- o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- o Toll free phone: 8002490000
- o E-mail: npc.drug@sdfa.gov.sa
- o Website: www.sdfa.gov.sa/npc

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in medicine, its benefits and risks. Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists