Fucidin®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Fucidin® ointment?

Fucidin® ointment contains the active ingredient Sodium fusidate. Fucidin® ointment is used to kill bacteria, especially those of the kind known as Staphylococci. ("Staph")

For more information, see Section 1. Why am I using Fucidin® ointment? in the full CMI.

2. What should I know before I use Fucidin® ointment?

Do not use if you have ever had an allergic reaction to Fucidin® ointment or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Fucidin® Ointment? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fucidin® ointment and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Fucidin[®] Ointment?

- The usual dose of Fucidin® Ointment without a covering dressing is to apply two or three times daily.
- The usual dose of Fucidin® Ointment with a covering dressing is one application daily is enough.
- The average treatment period is seven days. Some infections may require longer treatment.
- Regarding the affected area of skin, ask your doctor or pharmacist how much Fucidin® Ointment to apply, and how thickly to spread the Fucidin® Ointment.
- Always wash your hands after applying Fucidin Ointment, unless the area being treated is on the hand.

More instructions can be found in Section 4. How do I use Fucidin® ointment? in the full CMI.

5. What should I know while using Fucidin® Ointment?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Fucidin® ointment. Tell your doctor immediately If you get diarrhoea while using Fucidin® Ointment, or even if the diarrhoea occurs several weeks after Fucidin® Ointment has been stopped. If you become pregnant while using Fucidin® Ointment, tell your doctor immediately. If you are about to have any blood tests, tell your doctor that you are using Fucidin® Ointment as it may interfere with the results of some tests. 	
Things you should not do	 Do not give Fucidin® Ointment to anyone else, even if they appear to have the same condition as you. Do not take Fucidin® Ointment to treat any other complaints unless your doctor tells you to. 	
Driving or using machines		
Looking after your medicine	• Store Fucidin Ointment in a cool dry place where the temperature stays below 30°C.	

For more information, see Section 5. What should I know while using Fucidin® ointment? in the full CMI.

6. Are there any side effects?

Fucidin® Ointment can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

Fucidin® Ointment

Active ingredient(s): Sodium fusidate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Fucidin® Ointment. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Fucidin® Ointment.

Where to find information in this leaflet:

- 1. Why am I using Fucidin® ointment?
- 2. What should I know before I use Fucidin® Ointment?
- 3. What if I am taking other medicines?
- 4. How do I use Fucidin® ointment?
- 5. What should I know while using Fucidin® ointment?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Fucidin® Ointment?

Fucidin® Ointment contains the active ingredient Sodium fusidate.

Fucidin® Ointment This antibiotic is used to kill bacteria, especially those of the kind known as Staphylococci. ("Staph")

Staphylococci are bacteria that can cause severe infections.

Fucidin® Ointment is made to be put directly on skin and wounds. It treats skin and wound infections, especially those caused by Staphylococci. Fucidin® Ointment does not work against infections caused by viruses and other bacteria, which are resistant.

NOTE: Sodium fusidate, and the related **fusidic acid**, are antibiotics that can also be given to you as a tablet. The brand name for these products is also "Fucidin."

Your doctor may have prescribed Fucidin® Ointment for another reason. Ask your doctor why this medicine has been prescribed for you.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

In babies during the first month of life, sodium fusidate may cause serious side effects. Discuss with your doctor if Fucidin® Ointment is to be used to treat a baby.

2. What should I know before I use Fucidin® Ointment?

Warnings

Do not use Fucidin® Ointment if:

- you have an allergy or have had an adverse reaction to any medicine containing sodium fusidate or fusidic acid
- any of the ingredients listed at the end of this leaflet (see Product Description).
- Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- after 60 days of first opening the tube or expiry date printed on the pack whichever comes first, or
- if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

 you have a known allergy to Fucidin® Ointment, sodium fusidate, fusidic acid or any ingredients listed at the end of this leaflet.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Fucidin® Ointment or may affect how well Fucidin® Ointment works. You may need different amounts of your medicines, or you may need to take different medicines.

Fucidin® Ointment applied on the skin will not generally interfere with other antibacterial treatment, for example antibiotic tablets or injections.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Fucidin® Ointment.

4. How do I use Fucidin® Ointment?

How much to use

- The usual dose of Fucidin® Ointment without a covering dressing is to apply two or three times daily.
- The usual dose of Fucidin® Ointment with a covering dressing is one application daily is enough.
- The average treatment period is seven days. Some infections may require longer treatment.
- Regarding the affected area of skin, ask your doctor or pharmacist how much Fucidin® Ointment to apply, and how thickly to spread the Fucidin® Ointment.
- Always wash your hands after applying Fucidin® Ointment, unless the area being treated is on the hand
- In certain very serious infections, it may be necessary to take other antibiotics in addition to Fucidin® Ointment.
- Follow the instructions provided and use Fucidin® Ointment until your doctor tells you to stop.

When to take / use Fucidin® Ointment

- Use Fucidin® Ointment at about the same time each day:
- This ensures a steady antibiotic effect and helps you remember to use it.

How long to use Fucidin® Ointment

- Follow carefully all directions given to you by your doctor and the pharmacist. These directions may differ from the information contained in this leaflet.
- Continue using your medicine until your doctor tells you otherwise.
- Do not stop using this medicine because you are beginning to feel better. If you do not complete the course of antibiotic treatment the infection may return.
- If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

If you forget to use Fucidin® Ointment

Fucidin® Ointment should be used regularly at the same time each day. If you miss your dose and it is almost time for your next dose, skip the dose you missed and apply your next dose when you are meant to.

Otherwise, apply it as soon as you remember, and then go back to applying your medicine as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your doctor or pharmacist for some hints.

If you use too much Fucidin® Ointment

If you think that you have used too much Fucidin® Ointment, or if anyone swallows a quantity of Fucidin® Ointment, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. The person who has swallowed the Fucidin Ointment may need urgent medical attention.

5. What should I know while using Fucidin® Ointment?

Things you should do

Call your doctor straight away if you:

- •if you get diarrhoea while using Fucidin® Ointment, or even if the diarrhoea occurs several weeks after Fucidin® Ointment has been stopped.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Fucidin® Ointment.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are using Fucidin® Ointment.
- It may affect other medicines used during surgery.
- If you become pregnant while using Fucidin® Ointment, tell your doctor immediately. If you are about to have any blood tests, tell your doctor that you are using Fucidin® Ointment as it may interfere with the results of some tests.

Remind any doctor, dentist or pharmacist you visit that you are using Fucidin® Ointment.

Things you should not do

- Do not use Fucidin® Ointment to treat any other complaints unless your doctor tells you to.
- Do not give Fucidin® Ointment to anyone else, even if they appear to have the same condition as you.
- Do not stop using your medicine without checking with your doctor.

Things to be careful of

Be careful not to get Fucidin® Ointment in your eye, especially if you are treating your face or hands.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Fucidin® Ointment affects you.

Fucidin® Ointment is not expected to cause you any problems with driving or operating machinery. However, as with many other medicines, Fucidin® Ointment may cause dizziness, tiredness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

- Keep Fucidin® ointment in a cool dry place where the temperature stays below 30°C.
- Do not use Fucidin® Ointment after 60 days of first opening the tube or the expiry date printed on the pack, whichever comes first.
- Heat and dampness can destroy some medicines.
 Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it. A locked cupboard at least one-and a-half metres above the ground is a good place to store medicines.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Mild irritation or pain at the site of treatment Pain in leg ulcers Hypersensitivity (allergy) to sodium fusidate or fusidic acid or the ingredients of the ointment Itching and discharge of the eyes (conjunctivitis) gradual onset of itchiness, redness, rash, swelling or blistering of the skin 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects		What to do
•	severe and sudden onset of itching, redness, hives or a rash around the application area nausea or vomiting	Call your doctor straight away, or go straight to the Emergency

Swelling of the face, lips, mouth, tongue or throat with breathing difficulties
 difficulties
 Department at your nearest hospital if you notice any of these serious side effects.

Do not be alarmed by this list of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Fucidin® Ointment contains

Active ingredient (main ingredient)	Sodium Fusidate - 2% w/w (20mg/g)
Other ingredients	Cetyl alcohol
(inactive ingredients)	• Wool fat
	White soft paraffin
	Liquid paraffin

Do not take this medicine if you are allergic to any of these ingredients.

What Fucidin® Ointment looks like

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Fucidin® Ointment is supplied in tube of 5g (physician sample) and 15g. Not all pack sizes may be marketed.

The Australian Registration Number is AUST R 12990.

Who distributes Fucidin® Ointment

Fucidin® Ointment is supplied in Australia by: LEO Pharma Pty Ltd

Brisbane, QLD Australia

Toll free no: 1800 991 778

Web: www.leo-pharma.com.au

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