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® tablets?

Fucidin® tablets contains the active ingredient Sodium fusidate. Fucidin® tablets are used as an antibiotic which kills certain bacteria that can cause serious illness.

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

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

Do not use if you have ever had an allergic reaction to Fucidin® tablets 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® Tablets? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fucidin® tablets 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® Tablets?

- Swallow the tablets whole with a full glass of water, on an empty stomach.
- The usual dose of Fucidin® Tablets for skin conditions is 1 tablet (250mg) twice daily.
- For other infections, the adult dose is usually 2 tablets (500 mg) three times daily.
- The dose for children between 5 and 12 years of age is 1 tablet (250 mg) three times daily.
- In certain very serious infections, it may be necessary to take other antibiotics in addition to Fucidin® Tablets.

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

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

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Fucidin® tablets. Tell your doctor immediately If the symptoms of your infection do not begin to improve within a few days, or if they become worse. Tell your doctor if you become pregnant while you are taking Fucidin® Tablets and if you are about to start taking any new medicine while you are taking Fucidin® Tablets. 	
Things you should not do	 Do not give Fucidin® Tablets to anyone else, even if they have the same condition as you. Do not take Fucidin® Tablets to treat any other complaints unless your doctor tells you to. 	
Driving or using machines	Be careful driving or operating machinery until you know how Fucidin® Tablets affect you.	
Looking after your medicine	• Keep Fucidin® Tablets in the blister pack until it is time to take them. Keep your tablets 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® tablet? in the full CMI.

6. Are there any side effects?

Fucidin® Tablets 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. Some common side effects include nausea, vomiting, indigestion, diarrhoea, stomach or abdominal pain, wind, tiredness, headache, and skin rash.

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® Tablets 1

Fucidin® Tablets

Active ingredient(s): Sodium fusidate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Fucidin® Tablets. 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® Tablets.

Where to find information in this leaflet:

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

1. Why am I using Fucidin® Tablets?

Fucidin® Tablets contains the active ingredient Sodium fusidate.

Fucidin® Tablets contain an antibiotic which kills certain bacteria that can cause serious illness. Fucidin® Tablets are active against Staphylococci or "Staph", which can cause severe infections. Infection may occur in different parts of the body, for example, the lung, bone, blood, heart, joints, eyes, skin and wounds. This medicine may be used with other antibiotics to treat infections. Fucidin® Tablets will not work against infections caused by viruses, such as cold or flu, and certain other bacteria. This medicine is available only with a doctor's prescription. Your doctor may have prescribed Fucidin® Tablets for another reason. Ask your doctor why Fucidin® Tablets have been prescribed for you.

There is no evidence that this medicine is addictive.

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

Warnings

Do not use Fucidin® Tablets if:

- you are allergic to Sodium fusidate or fusidic acid, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Do not take this medicine if you are taking certain medicines for cholesterol lowering called statins or HMG-CoA reductase inhibitors. Ask your doctor if you are not sure if you are taking any of these medicines

Check with your doctor if you:

- have or have ever had any health problems or medical conditions, particularly any illnesses affecting your liver.
- are taking certain HIV medicines (HIV-protease inhibitors).
- have a rare birth condition of glucose or lactose intolerance
- have biliary disease, such as problems with the transport of bilirubin.

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.

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® Tablets.

4. How do I use Fucidin® Tablets?

How to take it

Swallow the tablets whole with a full glass of water

How much to take / use

- The usual dose of Fucidin® Tablets for skin conditions is 1 tablet (250 mg) twice daily.
- For other infections, the adult dose is usually 2 tablets (500 mg) three times daily.
- The dose for children between 5 and 12 years of age is 1 tablet (250 mg) three times daily.
- In certain very serious infections, it may be necessary to take other antibiotics in addition to Fucidin® Tablets.
- Follow the instructions provided and use Fucidin® Tablets until your doctor tells you to stop.

When to take / use Fucidin® Tablets

Fucidin® Tablets should be taken without food.

How long to use Fucidin® Tablets

- It is usually necessary to take a course of Fucidin® Tablets for between 5 and 10 days.
- Continue taking Fucidin® Tablets until you finish the pack unless your doctor recommends otherwise.
- Do not stop taking Fucidin® Tablets because you are feeling better.
- If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.

If you forget to use Fucidin® Tablets

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

Otherwise, take it as soon as you remember, and then go back to taking Fucidin® Tablets as you would normally. If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering to take Fucidin® Tablets, ask your doctor or pharmacist for some hints.

If you use too much Fucidin® Tablets

If you think that you have taken too many Fucidin® Tablets, 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.

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

Things you should do

Call your doctor straight away if you:

- if the symptoms of your infection do not begin to improve within a few days, or if they become worse.
- if you get severe diarrhoea whilst taking Fucidin® Tablets. Do this even if the diarrhoea occurs several weeks after Fucidin® Tablets has been stopped.
- if your urine becomes very dark, your bowel motions become very pale or your eyes or skin look yellow.
- if you become pregnant while you are taking Fucidin® Tablets.

• if you are about to start taking any new medicine while you are taking Fucidin® Tablets.

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

Things you should not do

- Do not give Fucidin® Tablets to anyone else, even if they have the same condition as you.
- Do not take Fucidin® Tablets to treat any other complaints unless your doctor tells you to.

Driving or using machines

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

Fucidin® Tablets generally do not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Fucidin® Tablets may cause drowsiness or tiredness in some people. If you have any of these symptoms, do not drive or operate machinery.

Looking after your medicine

- Keep Fucidin® Tablets in the blister pack until it is time to take them. Keep your tablets in a cool dry place where the temperature stays below 30°C.
- Heat and dampness can destroy some medicines.
- Keep Fucidin® Tablets where children cannot reach them. A locked cupboard at least one-and-a- half metres above the ground is a good place to store medicines.
- Do not use Fucidin® Tablets after the expiry date on the package.

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.

When to discard your medicine

If your doctor tells you to stop taking Fucidin® Tablets or the expiry date has passed, ask your pharmacist what to do with any Fucidin® Tablets that are 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.

Fucidin® Tablets 3

Less serious side effects

Less serious side effects	What to do
 Nausea Vomiting Indigestion Diarrhoea Stomach or abdominal pains Wind Tiredness Headaches Skin rash 	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
•	Temporary paralysis or weakness of muscles Muscle swelling or pain Itching with swelling or skin Rash Swelling of the face, lips, mouth or throat, difficulty in swallowing or breathing Skin rash, redness, or a widespread rash with blisters Peeling skin particularly around the mouth, throat, nose, eyes and/or genitals Flu-like symptoms (fever, headache, body ache) that are followed by a rash Stinging eyes Discomfort when swallowing.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Fucidin® Tablets can occasionally cause liver upsets which can produce jaundice (yellow skin).

This condition will almost always get better after you finish taking Fucidin® Tablets.

Tell your doctor if you notice any of the following:

- very dark urine
- very pale bowel motions
- yellowing of the whites of your eyes
- yellow skin.

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® Tablets contains

Active ingredient	Sodium Fusidate (250
(main ingredient)	mg)
Other ingredients	Microcrystalline cellulose
(inactive ingredients)	Crospovidone
	Hypromellose
	Lactose monohydrate
	Magnesium stearate
	dl-alpha-tocopherol
	Colloidal silica anhydrous
	Purified talc
	Titanium dioxide

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

Fucidin® Tablets do not contain gluten, tartrazine or any other azo dye.

What Fucidin® Tablets looks like

Fucidin® Tablets are white in colour and oval in shape. Available in a box of 36 tablets, supplied in blister strips, each of which contains 9 tablets.

The Australian Registration Number for Fucidin® Tablets is AUST R 125822.

Who distributes Fucidin® Tablets

Fucidin® Tablets is supplied in Australia by:

LEO Pharma Pty Ltd

Brisbane, QLD Australia

Toll free no: 1800 991 778

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