## **Consumer Medicine Information**

## What is in this leaflet?

This leaflet answers some common questions about Fucidin® Tablets. It does not contain all the available information. It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Fucidin® Tablets against the benefits the medicine is expected to have for you.

#### If you have any concerns about taking either of these medicines, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

## What Fucidin® Tablets are used for

Fucidin® Tablets contain an antibiotic which kills certain bacteria which 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 has been prescribed for you.

There is no evidence that this medicine is addictive.

### Before you take Fucidin® Tablets

### When you must not take it

# Do not take this medicine if you have an allergy 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 onthe skin.

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.

Do not take this medicine

- after the expiry date printed on the pack. If you take it after the expiry date it may have no effect at all, or worse, an unexpected effect.
- if the packaging is torn, doesn't look quite right or shows signs of tampering.

If the packaging is damaged or it is past the expiry date, return the medicine to your pharmacist for disposal.

If you are not sure whether you should start taking Fucidin® Tablets, talk to your doctor.

Before you start to take it Tell your doctor if you

- have any allergies to any other medicine or any other substances, such as foods, preservatives or dyes. This may include medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.
- 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.
- are pregnant or intend to become pregnant. Your doctor can discuss with you the risks and benefits of taking Fucidin® Tablets during pregnancy.
- are breast-feeding or plan to breastfeed. Your doctor can discuss with you the risks and benefits of taking Fucidin® Tablets when breast-feeding.

#### If you have not told your doctor about any of the above, tell him/her before you start taking this medicine.

#### Taking other medicines

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

Some medicines may interfere with Fucidin® Tablets.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Fucidin® Tablets.

## How to take Fucidin® Tablets

#### Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

## If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

# How much to take

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.

## How to take it

Swallow the tablets whole with a full glass of water.

#### When to take it

Fucidin® Tablets should be taken without food.

#### How long to take it

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 take it

If 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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of these medicines. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. If you take too much Fucidin® Tablets you may get stomach pain, heartburn or diarrhoea.

# While you are taking Fucidin® Tablets

Things you must do

- Tell your doctor immediately
- 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.

Tell any other doctors, dentists and pharmacists who treat you that you are taking Fucidin® Tablets.

Things you must 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.

Things to be careful of

#### Be careful driving or operating machinery 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.

### Side effects

Like all medicines, 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 side effects may not appear until weeks or months after you have started taking Fucidin® Tablets.

#### Tell your doctor or pharmacist if you have any unpleasant effects while you are taking Fucidin® Tablets even if you do not think the effect is connected with the medicine or is not listed in this leaflet.

Ask your doctor or pharmacist to answer any questions you may have.

#### Do not be alarmed by the following lists of side effects. You may not experience any of them.

Antibiotics act by killing bacteria. Your bowel contains bacteria, many of which perform a useful function. When taken by mouth, antibiotics kill some of the normal bacteria in the bowel and can cause nausea, vomiting or diarrhoea. Severe diarrhoea is rare and must be reported to your doctor.

The most common side effects which can sometimes occur after taking Fucidin® Tablets are:

- nausea
- vomiting
- indigestion
- diarrhoea
- stomach or abdominal pains
- wind
- tiredness
- headaches
- skin rash (note that a skin rash may also be a sign of a very serious side effect . Further information and instructions are provided below).

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.

#### If any of the following happen, stop taking Fucidin® Tablets and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- 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.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

#### Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

## After using Fucidin® Tablets

Tell your doctor or pharmacist if you have any side effects even if you have stopped taking Fucidin® Tablets.

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

## Storage

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.

Do not store Fucidin® Tablets, or any other medicine in the bathroom or near a sink. Do not leave them on a window sill or in the car.

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.

### Disposal

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.

### Product description

#### What it 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.

#### Ingredients

Each Fucidin® Tablet contains 250 mg of sodium fusidate as the active ingredient. They also contain:

- microcrystalline cellulose
- crospovidone
- hypromellose
- lactose monohydrate
- magnesium stearate
- dl-alpha-tocopherol
- colloidal silica anhydrous
- purified talc
- titanium dioxide.

They do not contain gluten, tartrazine or any other azo dye.

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

This is not all the information available on Fucidin® Tablets. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

## Supplier

Fucidin® Tablets are supplied in Australia by:

LEO Pharma Pty Ltd Level 3, Tower 1, 25 Montpelier Road Bowen Hills, QLD 4006

AUSTRALIA

And manufactured by:

Laboratoires LEO.

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