#### **Consumer Medicine Information**

#### What is in this leaflet

This leaflet answers some common questions about FLUCIL®.

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 receiving FLUCIL® against the benefits this medicine is expected to have for you.

## If you have any concerns about having this medicine, ask your doctor or pharmacist.

#### Keep this leaflet.

You may need to read it again.

#### What FLUCIL® is used for

FLUCIL® is an antibiotic used to treat some infections in different parts of the body caused by bacteria.

FLUCIL® will not work against infections caused by viruses, such as colds.

FLUCIL® is an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that are causing your infection.

Your doctor may have prescribed FLUCIL® for another reason. Ask your doctor why FLUCIL® has been prescribed for you.

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

There is no evidence that FLUCIL® is addictive.

#### Before you are given FLUCIL®

## When you must not be given it

#### Do not use FLUCIL® if:

- your skin and/or eyes have turned yellow (Jaundice) while, or soon after receiving flucloxacillin (FLUCIL®).
- you have an allergy to FLUCIL® or other penicillins.
- Some of the symptoms of an allergic reaction may include skin rash, itching and difficult breathing.
- you have had an allergic reaction to cephalosporins.
- You may have an increased chance of being allergic to FLUCIL® if you are allergic to cephalosporins.

If you are not sure whether you should be given FLUCIL®, talk to your doctor.

## Before you are given it

Flucloxacillin (FLUCIL®) can cause jaundice (yellowing of skin and/or eyes) and severe liver disease which may last for a long time. This reaction is more frequent in older patients (particularly those over 55 years of age) and those who receive the drug for more than 14 days.

#### You must tell your doctor if:

- you have an allergy to FLUCIL® or other penicillins.
- you have had any type of allergic reaction to cephalosporin medicines.

You may have an increased chance of being allergic to FLUCIL® if you are allergic to cephalosporins.

- you have any allergies to any other medicines 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.
- your skin and/or eyes have turned yellow (Jaundice) while, or soon after, receiving any antibiotics
- you have or have ever had any other health problems/medical conditions, including kidney or liver disease.
- 6. you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of using FLUCIL® during pregnancy.

7. you are breast-feeding or plan to breast-feed. Your doctor will discuss the risks and benefits of using FLUCIL® when breast-feeding.

If you have not told your doctor about any of the above, tell him/her before you are given FLUCIL®.

#### Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with FLUCIL®. These include probenecid (Benemid).

These medicines may be affected by FLUCIL®, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid whilst receiving FLUCIL®.

## Some antibiotics may decrease the effectiveness of some birth control pills.

Talk to your doctor about the need for an additional method of contraception whilst receiving FLUCIL®.

#### How FLUCIL® is given

FLUCIL® may be given in two ways:

- as a slow injection into a vein
- as a deep injection into a large muscle, a joint or the sac surrounding the lung.

FLUCIL® must only be given by a doctor or nurse.

Your doctor will decide what the dose is and for how long you will receive FLUCIL®. This depends on your infection and other factors, such as your weight. For most infections, FLUCIL® is usually given in divided doses throughout the day. Sometimes only a single dose of FLUCIL® is required for the treatment and prevention of certain infections.

#### If you have too much (overdose)

A very large overdose of FLUCIL® can cause brain upsets, including fits.

## After you have been given FLUCIL®

#### Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you develop itching with swelling or skin rash or difficulty breathing after you have been given FLUCIL®, contact your doctor immediately.

If you develop yellow eyes and/or skin (jaundice) while, or soon after receiving FLUCIL®, contact your doctor immediately.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs up to several weeks after FLUCIL® has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

# Do not take any diarrhoea medicine without first checking with your doctor.

If you get a sore white mouth or tongue after you have been given FLUCIL®, tell your doctor. Also tell your doctor if you get a vaginal itching or discharge. This may mean you have a fungal infection called thrush. Sometimes the use of FLUCIL® allows fungi to grow and the above symptoms to occur. FLUCIL® does not work against fungi.

If you become pregnant while you are receiving FLUCIL®, tell your doctor.

If you have to have any tests tell your doctor you have been given FLUCIL®. FLUCIL® may affect the results of some tests.

Tell any doctor, dentist or pharmacist who is treating you that you have been given FLUCIL®.

### Things to be careful of

Be careful driving or operating machinery until you know how FLUCIL® affects you. FLUCIL® generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, FLUCIL® may cause dizziness, drowsiness or tiredness in some people.

#### Side Effects

Check with your doctor as soon as possible if you have any problems whilst receiving FLUCIL®, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, FLUCIL® 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.

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

## Whilst being given FLUCIL®

#### Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:

- a severe rash
- wheezing
- irregular heart beat
- feeling faint
- yellow skin and/or eyes
- Tell your doctor if you notice any of the following:
- pain or redness at the site of injection
- oral thrush white, furry, sore tongue and mouth
- vaginal thrush sore and itchy vagina and/or discharge
- · a mild rash

Other side effects not listed above may also occur in some patients. These include very rare conditions such as blood, liver and kidney problems or fits.

#### After finishing FLUCIL®

Tell your doctor if your skin and/or eyes have turned yellow (Jaundice) while or soon after receiving flucloxacillin (FLUCIL®).

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after finishing treatment with FLUCIL®:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above

These are rare but serious side effects. FLUCIL® can change bacteria (which are normally present in the bowel and normally harmless) to multiply and therefore cause the above symptoms. You may need urgent medical attention.

Do not take any diarrhoea medicine without first checking with your doctor.

An illness consisting of a rash, swollen glands, joint pains and fever may occur about a week after treatment.

Tell your doctor if you notice any side effects.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. Ask your doctor or pharmacist if you are concerned.

## After receiving FLUCIL®

#### Storage

Keep FLUCIL® in a cool dry place where the temperature stays below 25°C.

## FLUCIL® description

### What it looks like

FLUCIL® Injection is a white to off-white powder which has to be dissolved in water before it is injected.

#### Ingredients

Flucloxacillin sodium, 500 mg and 1 g.

### The Australian Registration Numbers are:

500mg AUST R 90879 1g AUST R 90878

#### Sponsor

Aspen Pharmacare Australia Pty Limited 34-36 Chandos Street, St Leonards 2065 NSW Australia

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