#### **FLUCIL** oral solution

Flucloxacillin

#### **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 taking it against the benefits this medicine is expected to have for you.

## If you have any concerns about taking 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.

## Ask your doctor why FLUCIL has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

There is no evidence that  $\ensuremath{\mathsf{FLUCIL}}\xspace{1.5mu}{\mathbb{R}}$  is addictive.

#### Before you take it

When you must not be given it Do not take FLUCIL if:

- your skin and/or eyes have turned yellow (Jaundice) while, or soon after taking flucloxacillin (FLUCIL).
- you have an allergy to FLUCIL, other penicillins or any of the ingredients listed at the end of this leaflet. 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 start taking FLUCIL, talk to your doctor. Before you start to take it

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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 take the drug for more than 14 days.

#### You must tell your doctor if:

- you have an allergy to FLUCIL, other penicillins or any of the ingredients listed at the end of this leaflet.
- 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 taking any antibiotics.
- you have or have ever had any other health problems/ medical conditions, including kidney or liver disease.
- you are pregnant or intend to become pregnant.
- Your doctor will discuss the risks and benefits of using FLUCIL during pregnancy.
- you are breast-feeding or plan to breastfeed.

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 (Pro-Cid)
- paracetamol.

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 taking FLUCIL.

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

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

#### How to take it

#### Do not take FLUCIL if the packaging is torn or shows signs of tampering. Do not take FLUCIL if the expiry date on the pack has passed.

If you take it after the expiry date it may have no effect at all, or worse, an unexpected effect.

#### How much to take

Your doctor will choose the correct dose for you. The usual dose for adults is 250 mg every 6 hours, but this can be increased in severe infections. Children between 2 & 10 years of age should have half the adult dose and infants below 2 years of age should be given a quarter of the adult dose.

Your pharmacist will explain how many mLs of syrup will be needed to receive the correct dose.

Follow all directions given to you by your doctor and pharmacist carefully. These directions 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 to take it

FLUCIL oral solution is taken orally.

#### When to take it

FLUCIL oral solution should be taken a half to one hour before meals. If you are too ill to eat, take the medicine when it is due.

#### How long to take it

Continue taking it until you finish the bottle or unless your doctor recommends otherwise.

## Do not stop taking FLUCIL 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 FLUCIL 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.

If you have trouble remembering when to take FLUCIL, ask your pharmacist for some hints.

If you have too much (overdose) Consult your doctor if you think that your or anyone else may have taken too much FLUCIL. Do this even if there are no signs of discomfort or poisoning.

If you take too much FLUCIL, you may get diarrhoea and nausea.

#### While you are taking it

#### Things you must do

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

If you develop itching with swelling or skin rash or difficulty breathing while you are taking FLUCIL, do not take any more and contact your doctor immediately.

If you develop yellow eyes or skin (jaundice) while, or soon after taking

FLUCIL, tell your doctor immediately. If you get severe diarrhoea tell your

doctor or pharmacist immediately. Do this even if it occurs 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.

#### Tell your doctor if you become pregnant while you are taking FLUCIL.

If you have to have any tests tell your doctor you are taking FLUCIL. It may affect the results of some tests.

Tell any doctor, dentist or pharmacist who is treating you that you are taking FLUCIL.

#### Things you must not do

Do not give FLUCIL to anyone else, even if they have the same condition as you. Do not take FLUCIL 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 FLUCIL affects you. This medicine generally does not cause any problems with the 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 while taking 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 taking it

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:

- oral thrush white, furry, sore tongue and mouth
- vaginal thrush sore and itchy vagina and/or discharge
- a mild rash
- vomiting or an upset stomach
- diarrhoea

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 it

Tell your doctor if your skin and/or eyes have turned yellow (Jaundice) while or soon after taking flucloxacillin (FLUCIL). Tell your doctor immediately if you notice any of the following side effects, even if

#### they occur up to 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.

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 taking it

#### Storage

FLUCIL oral solution

Keep the solution in the bottle until it is time to take it.

The mixture should be stored between 2-8°C and used within 14 days.

#### Discard any mixture remaining when the treatment is completed.

Discard any mixture which is not used within 14 days.

Keep it where children cannot reach it. Disposal

#### If your doctor tells you to stop taking FLUCIL or it passes its expiry date, ask

your pharmacist what to do with any medicine that is left over.

Once the pharmacist has made up the solution, it must be used within 14 days.

#### Product description

#### What it looks like

The syrup is supplied to the pharmacist as a powder which is made up into a 125 mg/5mL or a 250 mg/5mL pineapple-flavoured solution.

#### Ingredients

- FLUCIL contains:
- flucloxacillin sodium
- saccharin sodium
- disodium edetate
- sodium benzoate
- sucrose
- sodium citrate
- ammonium glycyrrhizinate
- erythrosine
- pineapple flavour PI (12542)
- menthol flavour PI (11940).

Each gram of flucloxacillin sodium contains 2.2 mmol of sodium

The Australian Registration Numbers are:

125 mg/5 mL: AUST R 165731

250 mg/5 mL: AUST R 165005.

### Sponsor

Aspen Pharmacare Australia Pty Ltd 34-36 Chandos Street St Leonards NSW Date of preparation: 27 November 2019