

# FLOXSIG (*Flock-sig*)

*Flucloxacillin sodium*

---

## Consumer Medicine Information

---

### What is in this leaflet

This leaflet answers some common questions about FLOXSIG.

It does not contain all the available information.

It does not take place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking FLOXSIG against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What is FLOXSIG

The name of your medicine is FLOXSIG.

FLOXSIG is a type of antibiotic that belongs to

the group of medicines called penicillins.  
(*PEN-I-SIL-LINS*)

FLOXSIG contains *flucloxacillin sodium*.  
Flucloxacillin sodium is a type of penicillin.

FLOXSIG is available in two strengths: *FLOXSIG 250 mg capsules* and *FLOXSIG 500 mg capsules*.

### What is FLOXSIG used for

FLOXSIG is used to treat infections in different parts of the body caused by bacteria.

FLOXSIG works by killing the bacteria that are causing the infection.

These infections may affect the skin and skin structure, bones (osteomyelitis), or the chest (pneumonia).  
FLOXSIG is also used to treat wound infections and infected burns.

FLOXSIG will not work against infections caused by viruses such as colds or the flu.

Your doctor however, may have prescribed FLOXSIG for another purpose.

**Ask your doctor if you have any questions about why FLOXSIG has been prescribed for you.**

FLOXSIG is only available with a doctor's prescription.

### Before you take FLOXSIG

**Warning: Flucloxacillin can cause severe liver damage, particularly in older patients and those who take it for more than 14 days.**

*When you must not take it*

**Do not take FLOXSIG if you have ever had an allergic reaction to:**

- FLOXSIG or any other penicillin.
- any of the other ingredients in FLOXSIG listed at the end of this leaflet.
- **Cephalosporins**

There is an increased chance of being allergic

to FLOXSIG if you are or have been allergic to cephalosporins.

*Some symptoms of an allergic reaction may include urticaria or skin rash, itching, difficulty in breathing, swelling of the face and tongue.*

**Tell your doctor if you have suffered from any allergic conditions in the past due to the use of penicillin.**

**Tell your doctor if you have had a history of liver problems associated with the use of FLOXSIG, other medicine containing flucloxacillin or any other medicine.**

Examples of liver reactions include hepatitis and jaundice that result in yellowing of eyes or skin due to high concentration of bilirubin in blood or urine.

**Do not take FLOXSIG after the expiry date (EXP) printed on the pack.**

**Do not take FLOXSIG if the packaging is torn or shows signs of tampering or if the seal is broken.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure**

**whether you should start taking FLOXSIG, talk to your doctor.**

***Before you start to take it***

**You must tell your doctor if you are:**

- allergic to any other medicines, foods, dyes or preservatives.

**Tell your doctor if you are pregnant or intend to become pregnant.**

FLOXSIG is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits involved.

**Tell your doctor if you are breast-feeding or plan to breast-feed.**

FLOXSIG may pass into breast milk. Therefore, there is a possibility that the breast-fed baby may be affected. Your doctor will discuss the risks and benefits involved.

**Tell your doctor if you have or have had any of the following medical conditions:**

- asthma
- liver problems
- kidney problems
- gastrointestinal problems

**If you have not told your doctor about any of the above, tell them before you start taking FLOXSIG.**

***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 and FLOXSIG may interfere with each other.

These include:

- *Probenecid*, medicine used to treat gout or hyperuricaemia
- Oral contraceptives
- *Warfarin*, medicine used to prevent blood clots
- *Methotrexate*, medicine used to treat arthritis and some types of cancer

The above medicines may either reduce the effectiveness of FLOXSIG, reduce its own effectiveness, and/or react with FLOXSIG resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking FLOXSIG.

**How to take FLOXSIG**

**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 bottle, ask your doctor or pharmacist for help.**

***How much to take***

In adults, the usual dose is one FLOXSIG 250 mg capsule every six hours.

**The dose will depend on the type of treatment required for a patient.**

**Your doctor will decide on the number of doses needed each day and how long you will need to take FLOXSIG.**

***How to take it***

Take the required dose of FLOXSIG as instructed by your doctor or pharmacist.

***When to take it***

FLOXSIG should be taken on an empty stomach, half to one hour before food. It should be taken every six hours or as recommended by your doctor or pharmacist.

***How long to take it***

Your doctor or pharmacist will tell you how long to take FLOXSIG.

**Take the whole course of FLOXSIG until it is finished.**

**Do not stop taking FLOXSIG even if you feel better.**

Your infection and symptoms 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 your medicine as you would normally.**

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

**If you have trouble remembering to take FLOXSIG, ask your pharmacist for some hints.**

***If you take too much (overdose)***

**Immediately telephone your doctor or the Poisons**

**Information Centre (telephone 13 11 26) 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 FLOXSIG. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep the telephone numbers of these places handy.**

**While you are using FLOXSIG**

***Things you must do***

**Tell your doctor immediately if you develop dark urine, pale stools, or yellowing of the white of the eyes or skin while taking FLOXSIG. Do this even if it occurs several weeks after stopping FLOXSIG. Serious effects on the liver have been reported.**

**If your symptoms do not improve within a few days, or if they become worse, contact your doctor immediately.**

**If you develop any form of skin or vaginal rash and/or itching, difficulties in breathing or oral infection (thrush) while taking FLOXSIG, do not**

**take FLOXSIG any more. Contact your doctor immediately.**

**If you get diarrhoea, nausea or vomiting, tell your doctor immediately. Do this even if it occurs several weeks after you have stopped using FLOXSIG.**

*Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medicine to stop diarrhoea without first checking with your doctor.*

**If you become pregnant while you are taking FLOXSIG, tell your doctor immediately. If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking FLOXSIG.**

**Tell any other doctors, dentists and pharmacists who are treating you that you are taking FLOXSIG.**

**Tell your doctor if you feel that FLOXSIG is not helping your condition.**

**Tell your doctor if, for any reason, you have not used FLOXSIG exactly as prescribed. Otherwise, your doctor may think that**

the medicine was not effective and change your treatment unnecessarily.

#### ***Things you must not do***

**Do not stop taking FLOXSIG until it is finished.**

**Do not stop taking FLOXSIG even if you feel better.**

Your infection and symptoms may not clear completely.

**Do not give FLOXSIG to anyone else, even if they have the same condition as you.**

**Do not take FLOXSIG to treat any other complaints unless your doctor tells you to.**

Your doctor has prescribed FLOXSIG especially for you and your condition. If you use it for another condition, it may not work or make the condition worse.

#### ***Things to be careful of***

**Tell your doctor if you get a sore mouth or tongue, vaginal itching or discharges, while taking or after you have stopped taking FLOXSIG.**

This could be due to a fungal infection called *Thrush*. This may also result in fever and irritation

in the stomach. Sometimes, use of this medicine allows fungi to grow, as FLOXSIG is ineffective against fungi.

**Be careful driving or operating machinery until you know how FLOXSIG affects you.**

FLOXSIG generally does not affect your ability to drive a car or operate machinery. However, as with many other medicines, FLOXSIG may also cause dizziness, drowsiness and/or tiredness in some people.

#### **Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FLOXSIG.**

FLOXSIG helps most people with infections, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Flucloxacillin can cause severe liver damage, which can make the skin and eyes turn yellow in colour. Such a condition is called jaundice.**

**This is more likely to occur in older patients**

**and those who take flucloxacillin for more than 14 days. Immediately contact your doctor if you notice any symptoms of jaundice.**

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

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- diarrhoea
- nausea and/or vomiting
- abdominal pain
- indigestion
- abnormal taste
- hot flushes
- headaches
- dizziness
- fatigue
- white furry sore tongue and mouth (oral thrush)
- sore and itchy vagina and/or discharge (vaginal thrush)

**Tell your doctor as soon as possible if you notice any of the following:**

- skin rash
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- yellowing of the skin and/or eyes (jaundice)
- pale stools and dark urine
- severe watery or bloody

diarrhoea

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing

FLOXSIG may cause other side effects not listed above. If you have any other side effects, tell your doctor immediately.

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

**After using FLOXSIG**

### *Storage*

**Keep FLOXSIG capsules in the bottle they were provided in until it is time to take them.**

If you take the capsules out of the bottle, they may not keep well.

**Keep FLOXSIG capsules where young children cannot reach them.**

A locked cupboard at least one-and-a-half metres

above the ground is a good place to store medicines.

**Keep FLOXSIG capsules in a cool dry place where the temperature stays below 25°C.**

Protect from moisture.

**Do not store FLOXSIG or any other medicine in the bathroom or near a sink.**

**Do not leave FLOXSIG on a windowsill or in the car.** Heat and dampness can destroy some medicines.

### *Disposal*

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

### **Product description**

#### *What it looks like*

**FLOXSIG 250 mg capsules** are orange and red hard gelatin capsules, inscribed with SIGMA and 250 mg in black ink. The capsules contain a white to off-white powder. They are available in bottles of 24.

**FLOXSIG 500 mg capsules** are orange and red hard gelatin capsules, inscribed with SIGMA and 500 mg in black ink. The capsules contain a white to

off-white powder. They are available in bottles of 24.

capsules

***List of active ingredients***

**FLOXSIG 250 mg:** each capsule contains 250 mg of flucloxacillin (as flucloxacillin sodium).

**FLOXSIG 500 mg:** each capsule contains 500 mg of flucloxacillin (as flucloxacillin sodium).

***List of inactive ingredients***

- magnesium stearate
- gelatin
- sodium lauryl sulfate
- silicon dioxide
- titanium dioxide
- brilliant blue FCF  
CI42090
- quinoline yellow  
CI47005
- allura red AC CI16035

The ink used in the capsule printing (Opacode A-10259 black) contains vegetable-based carbon black.

**FLOXSIG 250 mg & 500 mg capsules do NOT contain gluten, sucrose, lactose, tartrazine or any other azo dyes.**

The Australian Product Registration numbers are:

- AUST R 70641 for FLOXSIG 250 mg capsules
- AUST R 70642 for FLOXSIG 500 mg

---

**SPONSOR**

---

Sigma Pharmaceuticals  
(Australia) Pty Ltd (A.C.N.  
004 118 594)  
96 Merrindale Drive  
Croydon Victoria 3136  
Australia

Telephone: 03 - 9839 2800

This leaflet was prepared in  
May 2002.