Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DICLOXSIG. 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 using DICLOXSIG against the benefits this medicine is expected to have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What DICLOXSIG is used for

The name of your medicine is DICLOXSIG. It contains the active ingredient dicloxacillin sodium

DICLOXSIG is a type of antibiotic that belongs to the group of medicines called penicillins.

DICLOXSIG Dicloxacillin sodium is a type of penicillin.

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

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

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

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

Your doctor may have prescribed this medicine for another purpose.

Ask your doctor or pharmacist if you have any questions about why DICLOXSIG has been prescribed for you.

A doctor's prescription is required for DICLOXSIG.

Before you take it

When you must not take it

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

- DICLOXSIG or any other penicillin.
- any of the other ingredients listed at the end of this leaflet.
- Cephalosporins

There is an increased chance of being allergic to DICLOXSIG if you are or have been allergic to cephalosporins.

Some symptoms of an allergic reaction may include urticaria, skin rash and itching.

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

Do not take this medicine if you have a history of liver problems associated with the use of DICLOXSIG or any other medicine.

Do not use it if the packaging shows sign of tampering or the seal is broken.

Do not use it after the expiry date printed on the pack has passed.

It may have no effect at all, or worse, it may give an entirely unexpected effect if you use after the expiry date.

Before you start to take it

You must tell your doctor if:

- you are allergic to any other medicines, foods, dyes or preservatives.
- you are pregnant or intend to become pregnant.
- you are breast feeding or plan to breast feed.
- you had or ever had asthma, kidney or any other health problems.

Like most medicines, DICLOXSIG is not recommended in pregnancy and during breast feeding. Your doctor will discuss the possible risks and benefits of taking DICLOXSIG during pregnancy and breast feeding.

Taking other medicines

Tell your doctor if you are taking the following medicines:

- Probenecid (for gout)
- Warfarin (an anticoagulant)
- Phenytoin (used to treat epilepsy)

Tell your doctor or pharmacist if you are taking any other medicines.

This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way other's work. Your doctor or pharmacist can tell you what to do when taking DICLOXSIG with other medicines.

Avoid drinking alcohol while taking DICLOXSIG and for several days after completing a course of treatment with DICLOXSIG.

How to take it

How much to take

In adults, the usual dose is one DICLOXSIG 250 mg capsule every six hours. For more severe infections the dose may be increased to one DICLOXSIG 500 mg capsule every six hours.

The dose will depend on the type of treatment required for a patient. Your doctor will decide the number of doses needed each day and how long you will need to take DICLOXSIG. These doses may differ from the usual doses shown in this leaflet.

Follow the instructions given by your doctor and Pharmacist and read the label carefully.

If you do not understand the instructions on the box or bottle, ask your doctor or pharmacist.

How to take it

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

When to take it

DICLOXSIG should be taken on an empty stomach, one or two hours 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 use DICLOXSIG.

Take the whole course of DICLOXSIG until it is finished.

Do not stop taking this medicine even if you feel better.

Your infection and symptoms may return.

If you forget to take it

If you forget to take DICLOXSIG, take it as soon as you remember and then go back to your normal dose times.

If it is almost time for your next dose, skip the dose you missed and take your next dose at the time it is due.

Do not take double dose to make up for the dose you missed.

If you have trouble remembering to take or give DICLOXSIG, ask your pharmacist for some hints.

If you take too much (overdose)

Telephone your doctor or Poisons Information Centre (phone 131126) if you think that you or anyone else may have taken too much DICLOXSIG. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers of these places handy.

There are unlikely to be any serious problems from an overdose of DICLOXSIG. But you must consult your doctor or Poison Information Centre.

While you are using it

Things you must do

Tell your doctor immediately if you develop dark urine, pale stools, yellowing of the white of the eyes or skin while taking DICLOXSIG.

Serious effects on the liver have been reported.

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

If you develop any form of skin or vaginal rash and/or itching, difficulties in breathing or oral infection (thrush) while taking DICLOXSIG, do not take this medicine anymore. Contact your doctor immediately.

Tell your doctor if you get diarrhoea, nausea or vomiting.

Consult your pharmacist or nurse in absence of your doctor. Do this even if it occurs several weeks after you have stopped using DICLOXSIG.

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 DICLOXSIG tell your doctor.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking DICLOXSIG. Tell all your doctor(s), dentist and pharmacist(s) who are treating you that you are taking DICLOXSIG.

Tell your doctor if you feel that DICLOXSIG is not helping your

Tell your doctor if, for any reason, you have not used DICLOXSIG 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 DICLOXSIG until it is finished.

Do not stop taking this medicine even if you feel better.

Your infection and symptoms may not clear completely.

Do not give your medicine to anyone else even if their symptoms seem similar to yours.

Do not use DICLOXSIG to treat other conditions unless your doctor tells you.

Your doctor has prescribed DICLOXSIG specifically 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 sore mouth or tongue, vaginal itching or discharge while taking or after you have stopped taking DICLOXSIG.

This could be due to a fungal infection called Thrush. This may also result in fever and irritation in stomach. Sometimes use of this medicine allows fungi to grow, as DICLOXSIG is ineffective against fungi.

Take care while driving or operating machinery until you know how DICLOXSIG affects you.

DICLOXSIG generally does not affect your ability to drive a car or operate machinery. However, as with many other medicines, DICLOXSIG 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 using DICLOXSIG.

DICLOXSIG helps most people with infections, but it may have some unwanted 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.

Tell your doctor if you notice any of the following and they worry you-

Adverse reactions reported by some people using DICLOXSIG include:

- diarrhoea
- nausea & vomiting
- abdominal pain
- skin rashes
- abnormal taste
- hot flushes
- difficulty in breathing
- headache, dizziness & fatigue.
- jaundice, pale stools or dark urine

DICLOXSIG may cause other adverse drug reactions not listed above.

If you have any other side effects, tell your doctor.

Do not be alarmed by this list of possible adverse drug reactions. You may not experience any of them.

After using it

Storage

Keep your medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines

Store DICLOXSIG capsules below 25°C. Protect from moisture.

Do not leave DICLOXSIG in the car or on window sills.

Heat can destroy some medicines.

If your doctor tells you to stop using DICLOXSIG or it has passed its expiry date, ask your pharmacist what to do with any DICLOXSIG left over.

Product Description

What it looks like

DICLOXSIG 250 mg capsules are white hard gelatine capsules.

The capsules contain a white to off-white

DICLOXSIG 500 mg capsules are light green and white hard gelatin capsules, The capsules contain a white to off-white

Active Ingredients

DICLOXSIG 250 mg: each capsule contains 250mg of dicloxacillin (as dicloxacillin sodium).

DICLOXSIG 500 mg:

each capsule contains 500mg of dicloxacillin (as dicloxacillin sodium).

Inactive Ingredients

DICLOXSIG 250 mg capsules contain the following inactive ingredients:

- silicon dioxide
- magnesium stearate
- gelatine
- titanium dioxide

DICLOXSIG 500 mg capsules contain the following inactive ingredients:

- silicon dioxide
- magnesium stearate
- gelatine
- titanium dioxide
- Patent blue V
- Quinoline Yellow

DICLOXSIG 250 mg & 500 mg capsules are preservative free and do not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

The Australian Product Registration numbers are:

- AUST R 162744 for DICLOXSIG 250 mg capsules. Each pack contains 24 capsules.
- AUST R 162745 for DICLOXSIG 500 mg capsules. Each pack contains 24 capsules.

SPONSOR

Aspen Pharma Pty Ltd 34-36 Chandos Street

St Leonards NSW 2065 Australia

This leaflet was revised in November 2009