

DBL™ Flucloxacillin Sodium for Injection

flucloxacillin Injection (floo-klox-a-SILL-in)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Flucloxacillin Sodium for Injection. It does not contain all the available information.

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

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

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

Keep this leaflet.

You may need to read it again.

What DBL Flucloxacillin Sodium for Injection is used for

This medicine is an antibiotic that is used for the treatment of infections in different parts of the body caused by bacteria.

This medicine belongs to a group of medicines known as the penicillins.

It works by killing the bacteria causing your infection or by stopping its growth.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you are given DBL Flucloxacillin Sodium for Injection

When you must not be given it

You must not be given DBL Flucloxacillin Sodium for Injection if you have an allergy to:

- flucloxacillin
- any other penicillins
- any of the ingredients listed at the end of this leaflet
- any medicines belonging to another group of antibiotics called the cephalosporins.

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 on the skin.

You must not be given this medicine if you have a history of liver problems that were associated with being treated with flucloxacillin sodium monohydrate in the past.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have or have had allergies to any other medicines, foods, preservatives or dyes.

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

- kidney disease
- liver disease.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

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

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 and flucloxacillin sodium monohydrate may interfere with each other. These include:

- paracetamol
- probenecid, a medicine used to treat gout
- aminoglycosides; a group of antibiotic medicines used to treat some infections.

These medicines may be affected by flucloxacillin, 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 and pharmacist may have more information on medicines to be careful with or avoid while you are being treated with this medicine.

How DBL Flucloxacillin Sodium for Injection is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors such as your weight.

How it is given

DBL Flucloxacillin Sodium for Injection is usually injected into a muscle or a vein, or into a lung cavity or joint. It should only be given by a doctor or nurse.

If you receive too much (overdose)

As DBL Flucloxacillin Sodium for Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience severe side effects after being given this medicine, tell your doctor immediately.

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 for advice, or go to Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DBL Flucloxacillin Sodium for Injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

While you are being given DBL Flucloxacillin Sodium for Injection

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 get severe diarrhoea tell your doctor or nurse immediately. Do this even if it occurs several weeks after flucloxacillin sodium monohydrate 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 receiving flucloxacillin sodium monohydrate, tell your doctor or nurse. Also tell your doctor or nurse if you get vaginal itching or discharge.

This may mean you have fungal infection called thrush. Sometimes the use of flucloxacillin allows fungi to grow and the above symptoms to occur. Flucloxacillin sodium monohydrate does not work against fungi.

If you become pregnant while you are being treated with this medicine tell your doctor.

Tell all other doctors, dentists and pharmacists who are treating you that you are being treated flucloxacillin.

Things to be careful of

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

This medicine does not generally cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, flucloxacillin may cause dizziness in some people.

If you experience dizziness, do not drive.

If you drink alcohol, dizziness may be worse.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with flucloxacillin.

This medicine helps treat infections in most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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

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

- pain, swelling, or redness around the injection site
- skin rash
- itchiness
- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- nausea (feeling sick)

- mild diarrhoea or constipation
- dizziness or headache
- pain or an uncomfortable feeling in the stomach or belching after eating.
- muscle cramps or weakness, feeling tired, constipation

The above list includes side effects which are usually mild.

Tell your doctor or nurse immediately if you notice any of the following:

- severe blisters and bleeding in the lips, eyes, mouth, nose or genitals
- itchy spots accompanied by fever and feeling unwell
- signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin
- fever
- severe diarrhoea
- yellowing of the skin and/or eyes (these may be symptoms of a type of liver disease called jaundice)
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine (these may be symptoms of a type of liver disease called hepatitis).
- tiredness, headaches, being short of breath when exercising, dizziness, looking pale.
- heart palpitations
- thirst, together with confusion or muscle twitching

The above list includes very serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor or nurse if you notice anything else that is making you feel unwell.

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

After finishing treatment with it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with flucloxacillin sodium monohydrate:

- 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. You may have a serious condition affecting your bowel. Therefore you may need urgent medical attention.

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

After you are given DBL Flucloxacillin Sodium for Injection

Storage

DBL Flucloxacillin Sodium for Injection will generally be stored in the pharmacy or on the ward. It is kept in a cool, dry place where the temperature stays below 25C, and is protected from light.

Product description

What it looks like

Flucloxacillin Sodium Monohydrate is a white or almost white powder.

DBL Flucloxacillin Sodium for Injection is available in packs of 5 vials.

Ingredients

Each vial of DBL Flucloxacillin Sodium for Injection (1 g) contains flucloxacillin sodium monohydrate

equivalent to 1 gram of flucloxacillin as the active ingredient. DBL Flucloxacillin Sodium for Injection does not contain any other ingredients.

DBL Flucloxacillin Sodium for Injection does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Supplier

DBL Flucloxacillin Sodium for Injection is supplied by:

Pfizer Australia Pty Ltd
Sydney NSW

Toll Free Number: 1800 675 229
www.pfizer.com.au

DBL Flucloxacillin Sodium for Injection is available in the following strengths and packs:

- Flucloxacillin Sodium Monohydrate equivalent to flucloxacillin 1 g in packs of 5 and 10 - AUST R 50579

This leaflet was updated in May 2020.

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