

## CONSUMER MEDICINE INFORMATION

### Flucloxin®

*flucloxacillin 250 mg, 500 mg and 1 g  
powder for solution for injection*

- Please read this leaflet carefully before you start using Flucloxin® injection.
- This leaflet answers some common questions about Flucloxin® 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 using Flucloxin® injection against the benefits they expect it will have for you.
- If you have any questions, concerns or experience any side effect, then talk to your doctor or pharmacist.
- Keep this leaflet with the medicine. You may need to read it again.

#### In this leaflet:

1. What is Flucloxin® and what is it used for
2. Before you are given Flucloxin® Injection
3. How Flucloxin® should be given
4. Possible side effects
5. How to store Flucloxin®
6. Further information

### 1. What is Flucloxin® and what is it used for?

Flucloxin® is an antibiotic which belongs to a group of medicines called penicillins. These medicines work by killing bacteria that cause infections. Flucloxin® Injection is used for the treatment of skin and soft tissue infections, for example: infections in joints or within the lining of the heart (endocarditis), respiratory tract or urinary tract or middle ear infections, infected blood and meningitis. It is also used to prevent infections that can occur during major surgical operations such as heart and lung operations (cardiothoracic surgery) and bone, joint and muscle operations (orthopaedic surgery). Your doctor may have prescribed Flucloxin® injection for another reason.

Ask your doctor if you have any questions about why Flucloxin® injection has been prescribed for you.

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

### 2. Before you take Flucloxin®

#### You should not be given Flucloxin® Injection if you:

- are allergic to flucloxacillin, cephalosporins, penicillin, or any other  $\beta$ -lactam antibiotic.
- have had liver problems or jaundice (yellow skin and whites of eyes) when you have been given flucloxacillin previously.

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

#### Tell your doctor before being given Flucloxin® Injection if you:

- have had any allergies especially to any other drugs (particularly penicillin or cephalosporins)
- are suffering from liver or kidney problems
- have heart failure
- taking other medicines: tell your doctor or nurse if taking any other medicines, including those you may have bought yourself without a prescription.

In particular check with your doctor if you are taking any of the following:

- Oral contraceptives that contain oestrogen- if you are using this type of medicine you should take additional precautions to prevent pregnancy
- Probenecid, a medicine taken to treat gout
- Methotrexate, medicine taken to treat cancer or autoimmune disorders
- Aminoglycosides – If Flucloxin® and an aminoglycoside are to be used simultaneously, the two antibiotics should not be mixed together.
- Certain other “bacteriostatic” antibiotics (antibiotics that stop bacteria growing but do not kill them), such as

chloramphenicol and tetracycline

- Paracetamol – there is a risk of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when flucloxacillin is used concomitantly with paracetamol, particularly in certain groups of patients at risk, e.g. patients with severe renal impairment, sepsis or malnutrition, especially if the maximum daily doses of paracetamol are used. High anion gap metabolic acidosis is a serious disease that must have urgent treatment.
- Voriconazole and Posaconazole – the simultaneous administration for flucloxacillin with either of the antifungals voriconazole or posaconazole may lead to decreased blood concentrations of the two antifungals. An increase in dose of the antifungals may be required.
- Various laboratory tests- Flucloxin® Injection may interfere with some tests.

If you have any doubts about whether you should be given this medicine then talk to your doctor.

**Special care should be taken in new-born or premature babies to avoid overdose or high levels of bilirubin, a chemical in the blood which can lead to brain damage.**

**Pregnancy and breast-feeding:**

You should let your doctor know immediately if you are pregnant or trying for a baby before this medicine is administered.

You should let your doctor know if you are breastfeeding or want to start breast-feeding before receiving Flucloxin® Injection.

**Driving and using machines:**

During treatment with Flucloxin® Injection, undesirable effects may occur which may influence the ability to drive and use machines.

**Sodium content**

Flucloxin® contains sodium and should be taken into consideration by patients on a controlled sodium diet.

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**3. How to take Flucloxin®**

Your doctor or nurse will prepare your injection by mixing the Flucloxin® Injection powder with a liquid such as water for injections, either in the vial or in another container. The mixture is usually injected into a muscle or into a vein where it will be given slowly over three to four minutes using a syringe or drip (infusion). In certain circumstances, it can also be injected directly into an infected joint or the chest wall. Dosage varies according to type of infection, severity and profile of the patient but the usual adult dose by intramuscular or intravenous injection is 250mg every six hours.

**Severe kidney disease**

If you have severe kidney failure you may be given a lower dosage. If you do not understand, or are in any doubt, ask your doctor or nurse.

Be aware superinfections may occur. This is a new infection resulting from the invasion of bacteria resistant to flucloxacillin. Flucloxin

should be discontinued and another therapy commenced.

If you think you may have received too much Flucloxin® Injection, please tell your doctor or nurse immediately.

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**4. Possible side effects of Flucloxin®**

Flucloxin® Injection, like all medicines, can cause side effects, although not everybody gets them. **You must inform your doctor immediately if the following symptoms occur as they may be a sign of an allergic or sensitivity reaction:**

• swelling of the face, throat or hands	• redness and blistering of the skin
• itching	• rash
• fever	• aching joints
• difficulty breathing	• kidney problems
• anaemia	• irregular heart beat
• feeling faint	• yellow skin and/or eyes
• oral thrush	• Vaginal thrush – sore and itchy vagina and/or discharge

**Also tell your doctor immediately if you develop any of the following:**

- severe diarrhoea: as Flucloxin® can affect the normal gut bacteria, causing a new infection (pseudomembranous colitis)
- upper abdomen tenderness which may indicate liver inflammation or jaundice- yellowing of skin or whites of the eye.

Very rare cases of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs

when there is an increase in plasma acidity, when flucloxacillin is used concomitantly with paracetamol, generally in the presence of risk factors.

If you get a sore white mouth or tongue after you have been given Flucloxin<sup>®</sup>, 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 Flucloxin<sup>®</sup> allows fungi to grow and the above symptoms to occur. Flucloxin<sup>®</sup> does not work against fungi.

**You should tell your doctor if you develop any of the symptoms above, even if they occur some weeks after you have stopped having the injections.**

If you become pregnant while you are receiving Flucloxin<sup>®</sup>, tell your doctor.  
If you have to have any tests tell your doctor you have been given Flucloxin<sup>®</sup>.  
Flucloxin<sup>®</sup> may affect the results of some tests.

Tell any doctor, dentist or pharmacist who is treating you that you have been given Flucloxin<sup>®</sup>.

Caution should be exercised when administering FLUCLOXIN to newly born or premature babies.

Flucloxacillin may cause hyperbilirubinaemia (high levels of bilirubin in the blood). Bilirubin is produced when red blood cells are broken down. Usually, the liver processes bilirubin but in new born and premature babies, the liver is not fully developed. High levels of bilirubin will cause

jaundice and may lead to brain damage. Babies using FLUCLOXIN<sup>®</sup> must be monitored closely.

FLUCLOXIN<sup>®</sup> remains in the body longer in newly born babies and the elderly due to incomplete or decreased kidney function. They are more likely to experience side effects.

During prolonged therapy, your doctor should carry out periodic tests to assess kidney and liver function and blood cell formation.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. By reporting side effects you can help provide more information on the safety of this medicine.

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#### **5. How to store Flucloxin<sup>®</sup>**

Flucloxin<sup>®</sup> Injection must be kept out of the reach and sight of children.

- Flucloxin<sup>®</sup> should not be used beyond the expiry date given on the vial.
- Your doctor, nurse or pharmacist will be responsible for storing and preparing Injection before use
- The medicine should not be used if it shows any signs of deterioration such as going cloudy.
- Store at or below 25°C.
- Once the solution has been diluted the product should be used immediately.

Ask your pharmacist how to dispose of Flucloxin<sup>®</sup> no longer required.

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#### **6. Further information**

##### **What Flucloxin<sup>®</sup> Injection contains**

Each vial contains 250mg, 500mg or 1g of the active ingredient flucloxacillin as sodium flucloxacillin monohydrate. There are no other ingredients.

Flucloxin<sup>®</sup> is a white powder for solution for injection.

Flucloxin<sup>®</sup> is available in packs of 5 or 10 vials. Not all pack sizes may be marketed.

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