The name of your medicine is "Flucloxacillin 250mg, 500mg, 1g Powder for Solution for Injection or Infusion" (referred to as Flucloxacillin Injection throughout this leaflet).

1. WHAT FLUCLOXACILLIN IS AND WHAT IT IS USED FOR

Your medicine contains the active substance flucloxacillin (as flucloxacillin sodium), which is one of a group of medicines called "penicillins". These medicines are also known as "antibiotics" and they work by killing the bacteria that cause infections.

Flucloxacillin injection is used to treat a wide range of bacterial infections which may include these affecting:

- The chest (pneumonia, emphysema and lung abscesses)
- Tonsils (tonsillitis, quinsy)
- Pharynx (pharyngitis)
- Sinuses (sinusitis)
- Tonsils (tonsillitis, quinsy)
- Skin and soft tissue (boils, abscesses, carbuncles, impetigo. Cellulitis, furunculosis, ulcers and acne)

Flucloxacillin injection can also be used to prevent infections following skin grafts or during major surgical procedures, particularly in heart or orthopaedic surgery.

2. BEFORE YOU ARE GIVEN FLUCLOXACILLIN INJECTION

Do not have Flucloxacillin Injection
You should not be given this medicine if:

- You are allergic to penicillin, cephalosporins or other antibiotics
- You have had jaundice (your skin and the whites of your eyes turn yellow) or you have had other liver problems when you have been given flucloxacillin previously.

You must tell your doctor or nurse if any of these apply to you.

Flucloxacillin should not be given into the eye.

3. HOW FLUCLOXACILLIN INJECTION IS GIVEN

Administration

- Intramuscular: Add 1.5 ml Water for Injections to 250 mg vial contents. Add 2 ml Water for Injections to 500 mg vial contents.
- Intravenous: Dissolve 250-500 mg in 5-10 ml Water for Injections. Dissolve 1 g in 15-20 ml Water for Injections. Administer by slow intravenous injection (three to four minutes). Flucloxacillin may also be added to infusion fluids or injected, suitably diluted, into the drip tube over a period of three to four minutes.

Intraperitoneal: Dissolve 250 mg in 5-10 ml Water for Injections.

Intra-articular: Dissolve 250-500 mg in up to 5 ml Water for Injections or 0.5% lidocaine hydrochloride solution.

Nebuliser solution: Dissolve 125-250 mg of the vial contents in 3 ml sterile water.

The following displacement volumes have been determined:

<table>
<thead>
<tr>
<th>Strength</th>
<th>Reconstitution volume</th>
<th>Displacement volume (approximate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>250 mg</td>
<td>1.5 - 10 ml</td>
<td>0.2 ml</td>
</tr>
<tr>
<td>500 mg</td>
<td>2 - 10 ml</td>
<td>0.35 ml</td>
</tr>
<tr>
<td>1 g</td>
<td>15 - 20 ml</td>
<td>0.6 ml</td>
</tr>
</tbody>
</table>
Surgical prophylaxis - 1 to 2 g IV at induction of doses six to eight hourly.

Osteomyelitis, endocarditis

The above systemic dosages may be doubled where necessary.

Intravenous

- 250 mg to 1 g four times a day.

For infections of the bones and joints (osteomyelitis) or the heart (endocarditis) – up to 8 g daily can be given in divided doses, every 6 to 8 hours.

To prevent infections after an operation, the usual dose is 1 to 2 g before the operation when you are given your anaesthetic.

This is then followed by 500 mg four times a day for up to 72 hours.

Primary prophylaxis

Children aged 10 years and below:

The usual dose for children aged two to ten is half the adult dose.

The usual dose for children under two years old is a quarter of the adult dose.

These doses can be increased in more serious infections.

If you are given more of this medicine than you should

This is unlikely to happen but if it does, the doctor will treat any symptoms that follow.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flucloxacillin Injection can cause side effects, although not everybody gets them.

If you get any of the following side effects soon after receiving this medicine, tell your doctor or nurse immediately. If you get them, you may have had a serious allergic reaction or other type of reaction to this medicine. You may need urgent medical attention:

• Stomach pain or diarrhoea (possibly with bleeding)
• Skin rash and itching
• Any unexplained bleeding or bruising or skin discolouration
• Skin rash and itching
• Blotching of the skin, mouth, eyes or genitals
• Any sudden wheeziness, difficulty in breathing or dizziness
• Any swelling of the face, neck or tongue.

Some of these reactions can be delayed for several weeks after finishing treatment.

The following side effects may also occur. Tell your doctor if any of these become troublesome.

Common side effects (probably affecting more than 1 in 100 people given this injection)

• Stomach upset.

Very Rare side effects (probably affecting fewer than 1 in 10,000 people given this injection)

• Reduction in blood cell counts which makes infections more likely
• Inflammation of the kidney which can cause swollen ankles or high blood pressure
• Joint pain, muscle pain or fever. This may develop after 2 days or more from the start of treatment
• Convulsions (“fits”) in patients taking high doses.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

5. HOW TO STORE FLUCLOXACILLIN INJECTION

Keep out of the reach and sight of children.

Store vials below 25°C. Your doctor, pharmacist or nurse will know how to store Flucloxacillin Injection properly.

Do not use after the expiry date which is printed on the label and carton, or if the powder shows signs of discolouration.

6. FURTHER INFORMATION

What Flucloxacillin injection contains

Each vial contains 250mg, 500mg or 1g of Flucloxacillin as (flucloxacillin sodium). There are no other ingredients.

What Flucloxacillin injection looks like and contents of the pack

Flucloxacillin injection is a white powder in a glass vial. Each carton contains 1, 5, 10, 20 or 50 glass vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder: Bovmed Limited, Unit 2, Eastman Way, Stevenage, Herts SG1 4SZ, UK

Manufacturer: Istituto Biochimico Italiano, 04011 Aprilia (Lt), Via di Fossignano, 2, Italy

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