The following information is intended for healthcare professionals only

Posology and Method of Administration

Posology

Depends on the age, weight and renal function of the patient, as well as the severity of the infection.

Adults:

Usual adult dosage (including elderly patients)
Intramuscular – 250 mg four times a day.
Intravenous – 250 mg to 1g four times a day

The above systemic dosages may be doubled where necessary;
Treatment of osteomyelitis, endocarditis – Up to 8g daily in divided doses six to eight hourly.
Surgical prophylaxis – 1 to 2g IV at induction of anaesthesia followed by 500mg six hourly IV, or IM for up to 72 hours.

Flucloxacillin may be administered by other routes in conjunction with systemic therapy.
Intrapleural – 250 mg once daily
By nebuliser – 125 to 250 mg four times a day.
Intra-articular – 250 to 500 mg once daily.

Paediatric population

Children*:*

Proportionately lower doses should be given in children.
Usual children's dosage
2-10 years: half adult dose
Under 2 years: quarter adult dose.

Abnormal renal function:

In common with other penicillins, Flucloxacillin usage in patients with renal impairment does not usually require dosage reduction. However, in the presence of severe renal failure (creatinine clearance <10 ml/min) a reduction in dose or an extension of dose interval should be considered. The maximum recommended dose in adults is 1 g every 8 to 12 hours.

Flucloxacillin is not significantly removed by dialysis and hence no supplementary dosages need to be administered either during, or at the end of the dialysis period.

Hepatic impairment

Dose reduction in patients with reduced hepatic function is not necessary.

Method of administration

Intramuscular:

Add 1.5 ml Water for Injections to 250 mg vial contents or 2 ml Water for Injections to 500 mg vial contents.

Intravenous *:*

Dissolve 250-500 mg in 5-10 ml Water for Injections or 1-2g 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.

Intrapleural*:*

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

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

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

PACKAGE LEAFLET: INFORMATION FOR THE USER
Flucloxacillin Sodium for Injection 250 mg, 500 mg, 1 g.

The name of your medicine is Flucloxacillin Sodium for Injection 250 mg, 500 mg, 1 g, which will be referred to as Flucloxacillin throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
• Keep this leaflet. You may need to read it again.
• If you have further questions, please ask your doctor or your nurse.
• If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Flucloxacillin is and what it is used for
2. What you need to know before you are given Flucloxacillin
3. How to use Flucloxacillin
4. Possible side effects
5. How to store Flucloxacillin
6. Contents of the pack and other information

1. What Flucloxacillin is and what it is used for

Flucloxacillin is an antibiotic belonging to the group known as penicillins. Antibiotics are used to kill the bacteria or "germs" which cause infections. Flucloxacillin can be given as an injection or breathed-in using a nebulizer (a device used to give a medicine as a liquid mist).

Flucloxacillin is given to treat a wide range of infections caused by bacteria which may include:
• skin and soft tissue (boils, abscesses, carbuncles, impetigo, cellulitis, furunculosis, ulcers, eczema and acne)
• wounds, burns, heart (endocarditis)
• ears (otitis media and otitis external)
• those affecting the chest (pneumonia, emphysema and lung abscess)
• sinuses (sinusitis)
• pharynx (pharyngitis)
• tonsils (tonsillitis, quinsy)
• bones and joints (osteomyelitis)
• gut (enteritis)
• membranes of the brain (meningitis)
• blood (septicaemia) and the kidney, bladder or the urethra (the tube which carries urine from the bladder).

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

2. What you need to know before you are given Flucloxacillin

You should not be given Flucloxacillin if you:
• are **allergic** to flucloxacillin or any other penicillin antibiotics (see symptoms section 4)
• have ever had an **allergic reaction to any of the other ingredients** of this medicine – see list of ingredients in section 6
• have had **liver** problems after taking this medicine (flucloxacillin)

Warning and precautions
Talk to your doctor before taking Flucloxacillin if you:
• suffer from **liver** problems
• suffer from **kidney** problems, as you may require a lower dose than normal
• are **50 years** or over
• have other **serious illnesses** (apart from the infection this medicine is treating)
• have human immunodeficiency virus (**HIV**)
• are taking or will be taking 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.

Other medicines and Flucloxacillin:
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:

• Probenecid(used to treat gout)
• The contraceptive pill as antibiotics can make these less effective (you will need to use extra precautions such as condoms while taking flucloxacillin and for a full 7 days after you finish taking it).
• Other antibiotics (used to treat infections)

Some medicines may affect the way others work. Always tell your doctor about all the medicines you are taking. This means medicines you have bought yourself as well as medicines on prescription from a doctor.

Pregnancy and breast-feeding:
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Tests
Regular monitoring of liver and kidney function should be performed whilst taking flucloxacillin for a long period of time. Tell your doctor that you are taking Flucloxacillin if you are having urine tests or blood tests because it may affect the results.

Driving and using machines:
There should be no effect on the ability to drive and operate machinery.

Important information about some of the ingredients of Flucloxacillin:
Flucloxacillin contains sodium (51 mg per gram). This should be taken into consideration if you are on a low sodium diet.

3. How to use Flucloxacillin.

Your medicine will usually be given to you by injection into the muscle (intramuscular) or injection into a vein (intravenous). It can also be given to you by injection into a joint (intra-articular) or injection into the lining of the lung (intrapleural), or by breathing in the medicine from a mask (nebuliser). Flucloxacillin should not be administered into the eye.

Flucloxacillin is usually given in a hospital by a doctor or nurse as an injection. Your doctor will decide how you are given Flucloxacillin and your dose.

The usual dose is:

Adults and elderly
Injections into the muscle (Intramuscular)
• 250 mg of Flucloxacillin four times a day

Injections into a vein (Intravenous)
• 250 mg to 1g of Flucloxacillin four times a day

The dose may be doubled for certain serious infections, when necessary.

For treatment of infections inside the bones (osteomyelitis) or infections inside the heart (endocarditis) the amount of flucloxacillin may be increased up to 8 g each day, and given in equal doses every six to eight hours.

Prevention of infection during operations
• between 1 g to 2 g, given into a vein, just as you receive your anaesthetic. A further dose of 500 mg every six hours will be given for up to 72 hours.

Flucloxacillin may be given in other ways when you are receiving other treatments at the same time. These are:
• into the lining of the lung (intrapleural injections) – 250 mg once daily.
• breathing the drug in through a mask (by nebuliser) – 125 to 250 mg four times a day.
• into an artery (intra-articular injections) – 250 to 500 mg once daily.
Flucloxacillin should not be given into the eye

Children aged 2-10 years
• half the adult dose

Children under 2 years
• one quarter of the adult dose

If you use more Flucloxacillin than you should
Your doctor or nurse will know how much to give you. If you think you have been given too much Flucloxacillin you should talk to your nurse or doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
STOP taking Flucloxacillin and contact your doctor straight away if you experience any of the following side effects:
• severe diarrhoea with bleeding
• notice your urine becoming darker or your faeces (otherwise known as poo) becoming paler
• notice your skin or the white of your eyes turning yellow
• notice any unexplained bleeding, bruising or skin discolouration
• convulsions (at high dosage)
• tiredness, breathlessness, light-headedness, a rapid weak pulse, palpitations or headaches, these may be signs of the destruction of red blood cells (causing anaemia).

Common side effects: may affect up to 1 in 10 people
• minor gastrointestinal disturbances e.g. stomach upset or diarrhoea.

Uncommon side effects – may affect up to 1 in 100 people
• allergic skin reactions e.g. 'hives' or 'nettle' rash. If you start to itch or get a rash tell your doctor or nurse at once, and treatment should be discontinued.

Very rare side effects – may affect up to 1 in 10,000 people
• hypersensitivity or severe allergic reaction including swollen face or breathing problems. An unexpected skin reaction, e.g. a rash and/or a sore mouth or eyes. Tell your doctor or nurse straight away if you notice any of these symptoms and STOP taking Flucloxacillin
• reduction (reversible) in blood cell counts
• inflammation of the kidney, bowel and/or liver. Liver problems may be severe and very rarely deaths have been reported (mainly in people with pre-existing liver problems or over 50's).
• joint or muscle pain. This may develop after 2 days or more from the start of treatment with Flucloxacillin
• fever. This may develop after 2 days or more from the start of treatment with Flucloxacillin
• burning sensation at the site of injection
• 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 (see section 2).

Not known: frequency cannot be estimated from the available data
•a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).
Contact a doctor immediately if you get any of these symptoms.

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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flucloxacillin

Your doctor or pharmacist will know how to store Flucloxacillin.

Flucloxacillin must be stored below 25 °C and kept in the original carton.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the label. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Flucloxacillin contains
The active substance is Flucloxacillin Sodium.

What Flucloxacillin looks like and contents of the pack
• Flucloxacillin comes in Type III uncoloured glass vials with rubber stoppers.
• It is available in pack sizes of 5, 10, 50 and 100 vials.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Kent Pharma UK Limited,
The Bower, 4 Roundwood Avenue,
Stockley Park, Heathrow,
United Kingdom,
UB11 1AF.

Manufacturer:
Mitim S.r.l
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