

Louth: Antimicrobial Guidelines - Louth Hospitals: Antimicrobial Guidelines: Neonatal - ■Flucloxacillin IV

Neonatal - Flucloxacillin IV

Flucloxacillin is a bactericidal penicillin antibiotic which is effective against staphylococci. Flucloxacillin is acid stable and can be given by mouth where appropriate. [1]

MEDICATION SAFETY ISSUES

- Special caution is essential in the newborn and neonates with renal impairment because of the potential for high serum levels of flucloxacillin due to a reduced rate of renal excretion.[2]
- Risk of kernicterus in jaundiced neonates when high doses given parenterally. [2]
- Cholestatic jaundice and hepatitis may occur very rarely, up to two months after treatment with flucloxacillin has stopped. Administration for more than 2 weeks and increasing age are risk factors. [1]

USES

Infections caused by beta-lactamase-producing staphylococci including otitis externa; as an adjunct in pneumonia, cellulitis and osteomyelitis and in staphylococcal meningitis and endocarditis [1].

PRESENTATION

Powder for solution for injection or infusion: Floxapen® 250mg and 500mg vials [2]

DOSAGE [1,3]

Age	Dose	Frequency	Max Dose
Neonate <7 days	50mg/kg	Every 12 hours	
Neonate 7 – 21 days	50mg/kg	Every 8 hours	
Neonate 21 – 28 days	50mg/kg	Every 6 hours	
Child 1 to 3 months	25mg/kg	Every 6 hours	Max 1g every 6 hours

Dose may be doubled for **severe infections** including osteomyelitis, endocarditis or suspected/confirmed staphylococcal meningitis [3]

RECONSTITUTION [3-6]

- **250mg vial** : Reconstitute 250mg vial with 4.8mL WFI (Displacement volume 0.2mL) to give a final concentration of 50mg/mL.
- **500mg vial** : Reconstitute 500mg vial with 4.7mL WFI (Displacement volume 0.3mL) to give 100mg/mL. **Further dilute** 5mL of this solution with 5mL of Sodium Chloride 0.9% or Glucose 5% (to a final volume of 10mL). The resulting solution contains flucloxacillin 50mg/mL.

ADMINISTRATION

Administer as either a slow IV injection over 3 – 5 minutes **OR** Add the required dose to a suitable volume of diluent (e.g. sodium chloride 0.9% or glucose 5%) and give as an IV infusion over 30 minutes [1,6].

SAMPLE CALCULATION

Two week old preterm neonate (1.1kg) with staphylococcal meningitis.

Dose = 100mg/kg every 8 hours = 110mg every 8 hours.

Reconstitute 250mg vial with 4.8ml WFI to give a concentration of 50mg/mL.

Withdraw 2.2mL (110mg) and give either as a slow IV injection or IV infusion over 30 minutes.

STORAGE

Do not store above 25 ° C. Once reconstituted, the product should be used immediately. [2]

MONITORING [1]

- Monitor liver function and renal function if high doses or prolonged courses.

- Hepatic disorders: Cholestatic jaundice may occur up to 2 months after treatment has stopped. Risk is increased with prolonged courses and increasing age.
- Renal impairment: Dosage reduction not usually required, use normal dose every 8 hours if severe renal impairment.

ADVERSE EFFECTS

Hypersensitivity reactions including urticaria, fever, joint pains, rashes, angioedema, anaphylaxis, serum sickness-like reactions; rarely CNS toxicity including convulsions (especially with high doses or in severe renal impairment), interstitial nephritis, haemolytic anaemia, leucopenia, thrombocytopenia and coagulation disorders; also reported diarrhoea (including antibiotic-associated colitis); also gastro-intestinal disturbances; *very rarely* hepatitis and cholestatic jaundice reported. [1]

REFERENCES

1. British Medical Association, Royal Pharmaceutical Society of Great Britain, Royal College of Paediatrics and Child Health, et al. BNF for Children. London: BMJ Group, Pharmaceutical Press and RCPCH Publications Limited; 2020. Available from www.medicinescomplete.com, accessed 17/11/2020.
2. Actavis Group. Floxapen 250mg Powder for solution for Injection or Infusion. 2018. Available from www.hpra.ie, accessed 17/11/2020.
3. Children's Health Ireland. Paediatric Formulary. Flucloxacillin Monograph. Available via smartphone application, accessed 17/11/2020.
4. Department of Health and Government of South Australia. South Australia Neonatal Medication Guidelines – Flucloxacillin 2018. Available from <http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+topics/neonatal+medication+guidelines>, accessed 17/11/2020.
5. Our Lady of Lourdes Hospital. Displacement values for injectable medicines, Oct 2019. On file in Pharmacy Department Z Drive, OLOL.
6. Medusa Injectable Drugs Guide. Flucloxacillin Intravenous – Paediatric Monograph, 2020. Available from www.medusa.wales.nhs.uk, accessed 17/11/2020.

Summary of Changes from Previous Versions

Date	Change
Feb 2021: Rev. No. 1	<p>Updated based on Rotunda Flucloxacillin Monograph Mar 2019. Changes to OLOL monograph:</p> <ul style="list-style-type: none"> • Monograph reworded to align with Rotunda monograph • Information on ORAL step down options as per Rotunda monograph were NOT added to OLOL monograph – oral switch can be decided if required on a case-by-case basis. • Dosage: Table on dose of IV flucloxacillin reformatted as per updated table in Rotunda monograph. • References updated.
Jan 2015	<p>This is the first version of this guideline. It is based on the Rotunda Hospital Neonatal Monograph for Flucloxacillin, Doc. No. 1, Revision No. 0, date of issue 10/11/14.</p> <p>Changes in OLOL monograph compared to the Rotunda monograph:</p> <ul style="list-style-type: none"> • Presentation/Reconstitution sections altered as a different brand and two strengths of flucloxacillin stocked in OLOL. • Dose range limited to children up to three months only in OLOL as monograph intended for use in NICU only. • Adverse Effects: full list from BNF for Children included.