

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Geriflox Elixir 125 mg/5 ml Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

When reconstituted as directed each 5 ml of elixir contains flucloxacillin sodium equivalent to 125 mg flucloxacillin.

Excipients:

Sucrose 3.1 g/5 ml

Sulphur dioxide (E220) 0.16 mg/5 ml

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

Pink, pineapple-flavoured granular powder for reconstitution as an oral solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Geriflox Elixir is indicated for the treatment of infections due to penicillinase producing staphylococci and other gram-positive organisms susceptible to this anti-infective.

4.2 Posology and method of administration

Geriflox Elixir is administered orally.

Oral forms of Flucloxacillin should be taken half to one hour before meals.

Recommended dosage schedules:

Adults and Children over 10 years

750 mg - 1500 mg daily in divided doses (i.e. 250 mg - 500 mg three times a day). This dosage may be doubled if necessary.

Children aged 2-10 years

The usual daily dose is 50mg/kg body weight in divided doses (or half the adult dose).

Children under 2 years:

A quarter of adult dose.

The dosage may be increased if necessary.

Special groups:

Geriflox Elixir usage in patients with renal impairment does not require dosage reduction. In the presence of severe renal failure (creatinine clearance < 10 ml/min) a reduction in dose or extension of dose interval should be considered. In high dose regimens the maximum recommended dose is 1g every 8 to 12 hours.

4.3 Contraindications

Geriflox Elixir should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g.

penicillins, cephalosporins) or excipients.

Geriflox Elixir is contraindicated in patients with a previous history of flucloxacillin- associated jaundice/hepatic dysfunction.

4.4 Special warnings and precautions for use

Serious and occasionally fatal hypersensitivity reactions (anaphylaxis) have been reported in patients receiving beta-lactam antibiotics. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral therapy. These reactions are more likely to occur in individuals with a history of beta-lactam hypersensitivity. If an allergic reaction occurs, flucloxacillin should be discontinued and the appropriate therapy instituted. Serious anaphylactoid reactions may require immediate emergency treatment with adrenaline. Oxygen, i.v steroids, and airway management, including intubation, may also be required.

Flucloxacillin should be used with caution in patients with evidence of hepatic dysfunction, those with serious underlying disease, and the elderly. In these patients, hepatic events may be severe, and in extremely rare circumstances, deaths have been reported.

Dosage should be adjusted in renal impairment (See Posology and Method of Administration).

Flucloxacillin is excreted in a manner similar to that for benzyl penicillin, i.e. by glomerular filtration and tubular secretion. This should be borne in mind when designing therapy.

Prolonged use of an anti-infective agent may result in the development of super-infection due to organisms resistant to that anti-infective.

During prolonged treatments (e.g. osteomyelitis, endocarditis), regular monitoring of hepatic renal function is recommended.

Special caution is essential in the newborn because of the risk of hyperbilirubinemia. Studies have shown that, at high dose following parenteral administration, flucloxacillin can displace bilirubin from plasma protein binding sites, and may therefore predispose to kernicterus in a jaundiced baby. In addition, special caution is essential in the newborn because of the potential for high serum levels of flucloxacillin due to a reduced rate of renal excretion.

Flucloxacillin has been associated with cholestatic jaundice, which may occur several weeks after stopping therapy (risk increase in those treated for longer than 2 weeks or who are over 55 years of age).

Flucloxacillin Elixir contains sodium benzoate which is a mild irritant to the skin, eyes and mucous membranes. It may cause jaundice in newborn babies.

Contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

As Flucloxacillin Elixir contains sucrose patients should be reminded to brush their teeth regularly.

4.5 Interaction with other medicinal products and other forms of interaction

Probenecid decreases the renal tubular secretion of flucloxacillin. Concurrent administration of probenecid delays the renal excretion of flucloxacillin.

In common with other antibiotics, flucloxacillin may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

Bacteriostatic drugs may interfere with the bactericidal action of flucloxacillin.

4.6 Fertility, pregnancy and lactation

Geriflox Elixir should not be used during pregnancy unless considered essential by the physician. The product is excreted in breast milk, presenting risk of candidiasis and also of central nervous system toxicity due to prematurity of the blood brain barrier. There is a theoretical possibility of later sensitisation.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The following convention has been utilised for the classification of undesirable effects: Very common ($>1/10$), common ($>1/100$, $<1/10$), uncommon ($>1/1000$, $<1/100$), rare ($>1/10,000$, $<1/1000$), very rare ($<1/10,000$)

Unless otherwise stated, the frequency of the adverse events has been derived from more than 30 years of post-marketing reports.

Blood and lymphatic systems disorders

Very rare: Neutropenia (including agranulocytosis) and thrombocytopenia. These are reversible when treatment is discontinued. Eosinophilia. Haemolytic anaemia.

Immune system disorders

Very rare: Anaphylactic shock (exceptional with oral administration) (see section 4.4), angioneurotic oedema.

If any hypersensitivity reaction occurs, the treatment should be discontinued. (See also Skin and subcutaneous tissue disorders).

Nervous system disorders

Very rare: In patients suffering from renal failure, neurological disorders with convulsions are possible with the LV. injection of high dose.

Gastrointestinal disorders

*Common: Minor gastrointestinal disturbances

Very rare: Pseudomembranous colitis

If pseudomembranous colitis develops, flucloxacillin should be discontinued and appropriate therapy, e.g. oral vancomycin should be initiated.

Hepato-biliary disorders

Very rare: Hepatitis and cholestatic jaundice (see section 4.4). Changes in liver function laboratory test results (reversible when treatment is discontinued).

Hepatitis and cholestatic Jaundice may be delayed for up to two months post-treatment. In some cases the course has been protracted and lasted for several months. Hepatic events may be severe, and in very rare circumstances, deaths have been reported. Most reports of deaths have been in patients ≥ 50 years of age in patients with serious underlying disease.

Skin and subcutaneous tissue disorders

*Uncommon: Rash, urticaria and purpura.

Very rare: Erythema multiforme, Stevens Johnson syndrome, and toxic epidermal necrolysis. (see also Immune system disorders).

Musculoskeletal and connective tissue disorders

Very rare: Arthralgia and myalgia sometimes develop more than 48 hours after the start of the treatment.

Renal and urinary disorders

Very rare: Interstitial nephritis.

This is reversible when treatment is discontinued.

General disorders and administration site conditions

Very rare: Fever sometimes develops more than 48 hours after the start of the treatment.

*The incidence of these adverse events (Aes) was derived from clinical studies involving a total of approximately 929 adult and paediatric patients taking flucloxacillin.

4.9 Overdose

There is no specific antidote for flucloxacillin. Gastric lavage and general supportive measures are advised.

5 PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

Pharmatherapeutic group: Beta lactamase resistant penicillins

ATC Code: J01CF05

Flucloxacillin is a penicillinase-resistant semi-synthetic penicillin resistant to gastric acid.

5.2 Pharmacokinetic properties

Peak serum concentrations are reached after one hour following an oral dose of 250 - 500 mg in fasting subjects. The total quantity absorbed by the oral route represents approximately 79% of the quantity administered.

Peak serum concentrations range from 3 - 27 micrograms/ml with a mean peak of 11 – 15 micrograms/ml. Therapeutic concentrations persist for about 4 hours.

Protein binding: the serum protein binding rate is 95%. Flucloxacillin diffuses well into most tissues.

Crossing the meningeal barrier: flucloxacillin diffuses in only small proportion into the cerebrospinal fluid of subjects whose meninges are not inflamed.

In normal subjects approximately 10% of the flucloxacillin administered is metabolised to penicilloic acid. The elimination half life of flucloxacillin is on the order of 53min.

Excretion occurs mainly through the kidney. 65% of the dose administered orally is recovered in unaltered active form in the urine within 8 hours. A small portion of the dose administered is excreted in the bile. The excretion of flucloxacillin is slowed in cases of renal failure.

5.3 Preclinical safety data

No further information available.

6 PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Sodium benzoate (E2II)

Disodium edetate

Saccharin sodium

Ammonium glycyrrhizate

Sodium citrate (E331)

Menthol flavour (containing sulphur dioxide (E220))

Pineapple flavour (containing sulphur dioxide (E220))
Sucrose
Erythrosine (E 127)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unreconstituted: 18 months
Reconstituted: 7 days

6.4 Special precautions for storage

Unreconstituted: Do not store above 25°C. Keep the bottle tightly closed.
Reconstituted: Store in a refrigerator (2°C to 8°C). Keep the bottle tightly closed.

6.5 Nature and contents of container

150 ml amber glass bottles with polypropylene screw cap or 150 ml high-density polyethylene bottles with tamper evident and child resistant closures - Polypropylene caps with uni-foam wad/liner - expanded polyethylene liner (Extruded closed cell foam produced from Low density Polyethylene) (LDPE) not faced with aluminium.
Each bottle contains sufficient powder to produce 100 ml Flucloxacillin Elixir 125 mg/5ml.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Pharmacist: To prepare, add 58 ml of potable water and shake until all powder is dissolved.

Patient: Shake well before each use. Use within seven days of preparation and discard any unused elixir. Keep the bottle tightly closed and store in a refrigerator (2°C-8°C).

7 MARKETING AUTHORISATION HOLDER

McDermott Laboratories Ltd.,
Trading as:
Gerard Laboratories
35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13

8 MARKETING AUTHORISATION NUMBER

PA 577/16/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 13th December 2006

10 DATE OF REVISION OF THE TEXT

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