

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

FLOXAPEN® Capsules 250mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Floxapen Capsules (Flucloxacillin Capsules BP) containing 250 mg flucloxacillin as Flucloxacillin Sodium BP.

3 PHARMACEUTICAL FORM

Floxapen Capsules: Black and caramel capsules overprinted with Floxapen.

4 CLINICAL PARTICULARS

Flucloxacillin is an isoxazolyl penicillin of the β -lactam group of antibiotics which exerts a bactericidal effect upon many Gram-positive organisms including β -lactamase-producing staphylococci and streptococci.

4.1 Therapeutic indications

Floxapen is indicated for the treatment of infections due to sensitive Gram-positive organisms, including β -lactamase-producing staphylococci and streptococci. Typical indications include:

Skin and soft tissue infections:

Boils	Cellulitis	Infected burns
Abscesses	Infected skin conditions,	Protection for skin
Carbuncles	e.g. ulcer, eczema, and acne	grafts
Furunculosis	Infected wounds	Impetigo

Respiratory tract infections:

Pneumonia	Lung abscess	Empyema
Sinusitis	Pharyngitis	Otitis media and externa
Tonsillitis	Quinsy	

Other infections caused by Floxapen-sensitive organisms:

Osteomyelitis	Urinary tract infection
Enteritis	Meningitis
Endocarditis	Septicaemia

Floxapen is also indicated for use as a prophylactic agent during major surgical procedures when appropriate; for example cardiothoracic and orthopaedic surgery.

Parenteral usage is indicated where oral dosage is inappropriate.

4.2 Posology and method of administration

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

Usual adult dosage (including elderly patients)

Oral - 250 mg four times a day.

Osteomyelitis, endocarditis - Up to 8 g daily, in divided doses six to eight hourly.

Surgical prophylaxis - 1 to 2 g IV at induction of anaesthesia followed by 500 mg six hourly IV, IM or orally for up to 72 hours.

Usual children's dosage

2-10 years: half adult dose.

Under 2 years: quarter adult dose.

Abnormal renal function: In common with other penicillins, Floxapen 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. Floxapen 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.

Administration

Oral: Oral doses should be administered half to one hour before meals.

4.3 Contraindications

Flucloxacillin should not be given to patients with a history of hypersensitivity to β -lactam antibiotics (e.g. penicillins, cephalosporins) or excipients.

Flucloxacillin is contra-indicated in patients with a previous history of flucloxacillin-associated jaundice/hepatic dysfunction.

4.4 Special warnings and precautions for use

Before initiating therapy with flucloxacillin, careful enquiry should be made concerning previous hypersensitivity reactions to β -lactams.

Serious and occasionally fatal hypersensitivity reactions (anaphylaxis) have been reported in patients receiving β -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 β -lactam hypersensitivity.

Flucloxacillin should be used with caution in patients with evidence of hepatic dysfunction, patients ≥ 50 years and those with serious underlying disease. In

these patients, hepatic events may be severe, and in very rare circumstances, deaths have been reported (see section 4.8).

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

Prolonged use may occasionally result in overgrowth of non-susceptible organisms.

Floxapen capsules contain approximately 51 mg sodium per g. This should be included in the daily allowance of patients on sodium restricted diets.

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

4.6 Pregnancy and lactation

Pregnancy: Animal studies with flucloxacillin have shown no teratogenic effects. The product has been in clinical use since 1970 and the limited number of reported cases of use in human pregnancy have shown no evidence of untoward effects. The decision to administer any drug during pregnancy should be taken with the utmost care. Therefore flucloxacillin should only be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

Lactation: Trace quantities of flucloxacillin can be detected in breast milk. The possibility of hypersensitivity reactions must be considered in breast-feeding infants. Therefore flucloxacillin should only be administered to a breast-feeding mother when the potential benefits outweigh the potential risks associated with the treatment.

4.7 Effects on ability to drive and use machines

Adverse effects on the ability to drive or operate machinery have not been observed.

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 ($>1/10,000, <1/1,000$), 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 system disorders

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

Immune system disorders

Very rare: Anaphylactic shock (exceptional with oral administration) (see Section 4.4 Special warnings and special precautions for use), angioneurotic oedema.

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

Gastrointestinal disorders

***Common:** Minor gastrointestinal disturbances.

Very rare: Pseudomembranous colitis.

If pseudomembranous colitis develops, flucloxacillin treatment 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 Special Warnings and Special Precautions for Use). Changes in liver function laboratory test results (reversible when treatment is discontinued). These reactions are related neither to the dose nor to the route of administration. The onset of these effects may be delayed for up to two months post-treatment; in several cases the course of the reactions has been protracted and lasted for some months. Hepatic events may be severe and in very rare circumstances a fatal outcome has been reported. Most reports of deaths have been in patients ≥ 50 years and 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 AEs was derived from clinical studies involving a total of approximately 929 adult and paediatric patients taking flucloxacillin.

4.9 Overdose

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically.

Flucloxacillin is not removed from the circulation by haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Properties: Flucloxacillin is a narrow-spectrum antibiotic of the group of isoxazolyl penicillins; it is not inactivated by staphylococcal β -lactamases.

Activity: Flucloxacillin, by its action on the synthesis of the bacterial wall, exerts a bactericidal effect on streptococci except those of group D (*Enterococcus faecalis*) staphylococci. It is not active against methicillin-resistant staphylococci.

5.2 Pharmacokinetic properties

Absorption: Flucloxacillin is stable in acid media and can therefore be administered either by the oral or parenteral route. The peak serum levels of flucloxacillin reached after one hour are as follows.

- After 250 mg by the oral route (in fasting subjects): Approximately 8.8 mg/l.
- After 500 mg by the oral route (in fasting subjects): Approximately 14.5mg/l.

- After 500 mg by the IM route: Approximately 16.5 mg/l.

The total quantity absorbed by the oral route represents approximately 79% of the quantity administered.

Distribution: Flucloxacillin diffuses well into most tissue. Specifically, active concentrations of flucloxacillin have been recovered in bones: 11.6 mg/l (compact bone) and 15.6 mg/l (spongy bone), with a mean serum level of 8.9 mg/l.

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

Crossing into mother's milk: Flucloxacillin is excreted in small quantities in mother's milk.

Metabolism: In normal subjects approximately 10% of the flucloxacillin administered is metabolised to penicilloic acid. The elimination half-life of flucloxacillin is in the order of 53 minutes.

Excretion: Excretion occurs mainly through the kidney. Between 65.5% (oral route) and 76.1% (parenteral route) of the dose administered 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.

Protein binding: The serum protein-binding rate is 95%.

5.3 Preclinical safety data

No further information of relevance to add.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Floxapen Capsules: Magnesium stearate, black iron oxide (E172), titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172).

6.2 Incompatibilities

None known.

6.3 Shelf life

Tray foil blister: 24 months
Fibreboard drums: 36 months

6.4 Special precautions for storage

Floxapen Capsules in Original Packs should be stored in a dry place.
Floxapen Capsules in reclosable containers should be stored in a cool, dry place. Fibreboard drums should be kept tightly closed in a cool, dry place.

6.5 Nature and contents of container

Floxapen Capsules 250 mg: Aluminium canister - 20, 50, 100 and 500; Glass bottle with screwcap - 20, 50, 100 and 500; Polypropylene tube with polyethylene closure - 20, 50, 100 and 500; Aluminium foil – 12; Aluminium/PVC Blister with an aluminium overseal (tray foil blister pack) – 28; Fibreboard drum with metal or HDPE lid – 50,000

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Actavis Group PTC ehf
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland.

8 MARKETING AUTHORISATION NUMBER(S)

MA628/01101

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1 November 2006

10 DATE OF REVISION OF THE TEXT

22 November 2007

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3 PHARMACEUTICAL FORM

Floxapen Capsules: Black and caramel capsules overprinted with Floxapen.

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Flucloxacillin should be used with caution in patients with evidence of hepatic dysfunction, patients ≥ 50 years and those with serious underlying disease. In

these patients, hepatic events may be severe, and in very rare circumstances, deaths have been reported (see section 4.8).

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

Prolonged use may occasionally result in overgrowth of non-susceptible organisms.

Floxapen capsules contain approximately 51 mg sodium per g. This should be included in the daily allowance of patients on sodium restricted diets.

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

4.6 Pregnancy and lactation

Pregnancy: Animal studies with flucloxacillin have shown no teratogenic effects. The product has been in clinical use since 1970 and the limited number of reported cases of use in human pregnancy have shown no evidence of untoward effects. The decision to administer any drug during pregnancy should be taken with the utmost care. Therefore flucloxacillin should only be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

Lactation: Trace quantities of flucloxacillin can be detected in breast milk. The possibility of hypersensitivity reactions must be considered in breast-feeding infants. Therefore flucloxacillin should only be administered to a breast-feeding mother when the potential benefits outweigh the potential risks associated with the treatment.

4.7 Effects on ability to drive and use machines

Adverse effects on the ability to drive or operate machinery have not been observed.

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 ($>1/10,000, <1/1,000$), 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 system disorders

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

Immune system disorders

Very rare: Anaphylactic shock (exceptional with oral administration) (see Section 4.4 Special warnings and special precautions for use), angioneurotic oedema.

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

Gastrointestinal disorders

***Common:** Minor gastrointestinal disturbances.

Very rare: Pseudomembranous colitis.

If pseudomembranous colitis develops, flucloxacillin treatment 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 Special Warnings and Special Precautions for Use). Changes in liver function laboratory test results (reversible when treatment is discontinued). These reactions are related neither to the dose nor to the route of administration. The onset of these effects may be delayed for up to two months post-treatment; in several cases the course of the reactions has been protracted and lasted for some months. Hepatic events may be severe and in very rare circumstances a fatal outcome has been reported. Most reports of deaths have been in patients ≥ 50 years and 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 AEs was derived from clinical studies involving a total of approximately 929 adult and paediatric patients taking flucloxacillin.

4.9 Overdose

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically.

Flucloxacillin is not removed from the circulation by haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Properties: Flucloxacillin is a narrow-spectrum antibiotic of the group of isoxazolyl penicillins; it is not inactivated by staphylococcal β -lactamases.

Activity: Flucloxacillin, by its action on the synthesis of the bacterial wall, exerts a bactericidal effect on streptococci except those of group D (*Enterococcus faecalis*) staphylococci. It is not active against methicillin-resistant staphylococci.

5.2 Pharmacokinetic properties

Absorption: Flucloxacillin is stable in acid media and can therefore be administered either by the oral or parenteral route. The peak serum levels of flucloxacillin reached after one hour are as follows.

- After 250 mg by the oral route (in fasting subjects): Approximately 8.8 mg/l.
- After 500 mg by the oral route (in fasting subjects): Approximately 14.5mg/l.

- After 500 mg by the IM route: Approximately 16.5 mg/l.

The total quantity absorbed by the oral route represents approximately 79% of the quantity administered.

Distribution: Flucloxacillin diffuses well into most tissue. Specifically, active concentrations of flucloxacillin have been recovered in bones: 11.6 mg/l (compact bone) and 15.6 mg/l (spongy bone), with a mean serum level of 8.9 mg/l.

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

Crossing into mother's milk: Flucloxacillin is excreted in small quantities in mother's milk.

Metabolism: In normal subjects approximately 10% of the flucloxacillin administered is metabolised to penicilloic acid. The elimination half-life of flucloxacillin is in the order of 53 minutes.

Excretion: Excretion occurs mainly through the kidney. Between 65.5% (oral route) and 76.1% (parenteral route) of the dose administered 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.

Protein binding: The serum protein-binding rate is 95%.

5.3 Preclinical safety data

No further information of relevance to add.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Floxapen Capsules: Magnesium stearate, black iron oxide (E172), titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172).

6.2 Incompatibilities

None known.

6.3 Shelf life

Tray foil blister: 24 months
Fibreboard drums: 36 months

6.4 Special precautions for storage

Floxapen Capsules in Original Packs should be stored in a dry place.
Floxapen Capsules in reclosable containers should be stored in a cool, dry place. Fibreboard drums should be kept tightly closed in a cool, dry place.

6.5 Nature and contents of container

Floxapen Capsules 250 mg: Aluminium canister - 20, 50, 100 and 500; Glass bottle with screwcap - 20, 50, 100 and 500; Polypropylene tube with polyethylene closure - 20, 50, 100 and 500; Aluminium foil – 12; Aluminium/PVC Blister with an aluminium overseal (tray foil blister pack) – 28; Fibreboard drum with metal or HDPE lid – 50,000

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Actavis Group PTC ehf
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland.

8 MARKETING AUTHORISATION NUMBER(S)

MA628/01101

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1 November 2006

10 DATE OF REVISION OF THE TEXT

22 November 2007

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

FLOXAPEN® Syrups

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Floxapen Syrups (Flucloxacillin Oral Suspension BP) when reconstituted each 5 ml contains 250 mg flucloxacillin as Flucloxacillin Magnesium BP.

3 PHARMACEUTICAL FORM

Floxapen Syrups: Bottles containing powder for the preparation of suspension.

4 CLINICAL PARTICULARS

Flucloxacillin is an isoxazolyl penicillin of the β -lactam group of antibiotics which exerts a bactericidal effect upon many Gram-positive organisms including β -lactamase-producing staphylococci and streptococci.

4.1 Therapeutic indications

Floxapen is indicated for the treatment of infections due to sensitive Gram-positive organisms, including β -lactamase producing staphylococci and streptococci. Typical indications include:

Skin and soft tissue infections:

Boils	Cellulitis	Infected burns
Abscesses	Infected skin conditions,	Protection for skin
Carbuncles	e.g. ulcer, eczema, and acne	grafts
Furunculosis	Infected wounds	Impetigo

Respiratory tract infections:

Pneumonia	Lung abscess	Empyema
Sinusitis	Pharyngitis	Otitis media and externa
Tonsillitis	Quinsy	

Other infections caused by Floxapen-sensitive organisms:

Osteomyelitis	Urinary tract infection
Enteritis	Meningitis
Endocarditis	Septicaemia

Floxapen is also indicated for use as a prophylactic agent during major surgical procedures when appropriate; for example cardiothoracic and orthopaedic surgery.

Parenteral usage is indicated where oral dosage is inappropriate.

4.2 Posology and method of administration

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

Usual adult dosage (including elderly patients)

Oral - 250 mg four times a day.

Usual children's dosage

2-10 years: half adult dose

Under 2 years: quarter adult dose.

Abnormal renal function: In common with other penicillins, Floxapen 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. Floxapen 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.

Administration

Oral: Oral doses should be administered half to one hour before meals.

4.3 Contraindications

Flucloxacillin should not be given to patients with a history of hypersensitivity to β -lactam antibiotics (e.g. penicillins, cephalosporins) or excipients.

Flucloxacillin is contra-indicated in patients with a previous history of flucloxacillin-associated jaundice/hepatic dysfunction.

4.4 Special warnings and precautions for use

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Flucloxacillin should be used with caution in patients with evidence of hepatic dysfunction, patients ≥ 50 years and those with serious underlying disease. In these patients, hepatic events may be severe, and in very rare circumstances, deaths have been reported (see section 4.8).

Special caution is essential in the newborn because of the risk of hyperbilirubinaemia. 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.

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

Prolonged use may occasionally result in overgrowth of non-susceptible organisms.

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

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Lactation: Trace quantities of flucloxacillin can be detected in breast milk. The possibility of hypersensitivity reactions must be considered in breast-feeding infants. Therefore flucloxacillin should only be administered to a breast-feeding mother when the potential benefits outweigh the potential risks associated with the treatment.

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Blood and lymphatic system disorders

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

Immune system disorders

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

Gastrointestinal disorders

*Common: Minor gastrointestinal disturbances.
Very rare: Pseudomembranous colitis.
If pseudomembranous colitis develops, flucloxacillin treatment 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 Special Warnings and Special Precautions for Use). Changes in liver function laboratory test results (reversible when treatment is discontinued).
These reactions are related neither to the dose nor to the route of administration. The onset of these effects may be delayed for up to two months post-treatment; in several cases the course of the reactions has been protracted and lasted for some months. Hepatic events may be severe and in very rare circumstances a fatal outcome has been reported. Most reports of deaths have been in patients ≥ 50 years and in patients with serious underlying disease.

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- After 500 mg by the IM route: Approximately 16.5 mg/l.

The total quantity absorbed by the oral route represents approximately 79% of the quantity administered.

Distribution: Flucloxacillin diffuses well into most tissue. Specifically, active concentrations of flucloxacillin have been recovered in bones: 11.6 mg/l (compact bone) and 15.6 mg/l (spongy bone), with a mean serum level of 8.9 mg/l.

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

Crossing into mothers' milk: Flucloxacillin is excreted in small quantities in mothers' milk.

Metabolism: In normal subjects approximately 10% of the flucloxacillin administered is metabolised to penicilloic acid. The elimination half-life of flucloxacillin is in the order of 53 minutes.

Excretion: Excretion occurs mainly through the kidney. Between 65.5% (oral route) and 76.1% (parenteral route) of the dose administered 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.

Protein binding: The serum protein-binding rate is 95%.

5.3 Preclinical safety data

No further information of relevance to add.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Floxapen Syrups: Saccharin sodium, xanthan gum, citric acid, sodium citrate, sodium benzoate, blood orange, tutti frutti, menthol dry flavours and sucrose.

6.2 Incompatibilities

None known.

6.3 Shelf life

Floxapen Syrups: Two years (following reconstitution: 14 days).

6.4 Special precautions for storage

Floxapen Syrups: Do not store above 25°C.
Once dispensed, Floxapen Syrups (bottles) remain stable for 14 days stored in a refrigerator (5°C).

6.5 Nature and contents of container

Floxapen Syrup 250 mg/5 ml: Clear glass bottles, reconstituted volume of 61 ml or 100 ml.

6.6 Special precautions for disposal

If a dilution of the reconstituted syrup is required, Syrup BP should be used.

7 MARKETING AUTHORISATION HOLDER

Actavis Group PTC ehf
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland.

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