AUSTRALIAN PRODUCT INFORMATION

FISAMOX®

(amoxicillin sodium) powder for injection

1 NAME OF THE MEDICINE

Amoxicillin sodium

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each FISAMOX vial contains 1000 mg of amoxicillin (as amoxicillin sodium) as the active ingredient.

3 PHARMACEUTICAL FORM

The powder for injection is a fine white to off-white homogenous powder.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

FISAMOX is indicated in the treatment of infections due to susceptible strains of the organisms listed below. FISAMOX is intended for use where the patient's condition precludes the administration of the oral form. Therapy should be guided by bacteriological studies, including sensitivity tests, and by clinical response. However, in emergency cases where the causative organism has not yet been identified, therapy with amoxicillin may be useful. Clinical judgement will decide whether combination with another antibiotic would provide a sufficiently broad spectrum of activity pending sensitivity test results.

Septicaemia (bacterial)

H. influenzae, E. coli (see Section 5.1 PHARMACODYNAMIC PROPERTIES), *P. Mirabilis,* Streptococcus, *S. pneumoniae, S. faecalis* and *Salmonella typhi*.

Skin and Skin Structure

Streptococci, non-β-lactamase-producing Staphylococci, *E. coli* (see Section 5.1 PHARMACODYNAMIC PROPERTIES).

Respiratory, acute and chronic

H. influenzae, Streptococci, *S. pneumoniae*, non-β-lactamase-producing Staphylococci, *E. coli* (see Section 5.1 PHARMACODYNAMIC PROPERTIES).

Genito-urinary Tract (complicated and uncomplicated), acute and chronic

E. coli (see Section 5.1 PHARMACODYNAMIC PROPERTIES), *P. mirabilis* and *S. faecalis*.

Gonorrhoea

N. gonorrhoeae (non-β-lactamase-producing)

Prophylaxis of Endocarditis

FISAMOX may be used for the prophylaxis of bacterial endocarditis in individuals at particular risk, such as those with prosthetic heart valves or those who have previously had endocarditis.

4.2 DOSE AND METHOD OF ADMINISTRATION

FISAMOX may be given by:

- intramuscular injection
- intravenous infusion

- SLOW intravenous injection

Dosage in Normal Renal Function

Upper Respiratory Tract Infections; Genito-urinary Tract Infections; Skin and Skin Structure Infections

Adults - 250 mg every 6 to 8 hours, depending on the patient's condition.

Children (under 20 kg) – 20 mg/kg/day in equally divided doses every 6 to 8 hours

In severe infections, or those caused by less susceptible organisms, 500 mg every 6 to 8 hours for adults and 40 mg/kg/day in equally divided doses every 6 to 8 hours for children may be needed.

Lower Respiratory Tract Infections

Adults – 500 mg every 6 to 8 hours.

Children (under 20 kg) – 40 mg/kg/day in equally divided doses every 6 to 8 hours.

Bacterial Septicaemia

In more serious infections in adults, FISAMOX can be given as 1000 mg every 6 hours, slow IV injection (taking 3 to 4 minutes if injecting directly or into drip tube) or IV infusion over a period of 0.5 to 1 hour.

Children (under 20 kg) - 20 to 40 mg/kg every 6 hours.

Dosage Adjustment in Renal Impairment

In renal impairment, the excretion of the antibiotic will be delayed and, depending on the degree of impairment, it may be necessary to reduce the total daily dosage (see Table 1)

Table 1

Infections Complicated by Renal Insufficiency **Creatinine clearance mL/min**	**Dosage Recommendations (for IV administration only in adults)**
Over 30	No adjustment required
10 to 30	1000 mg initially, then 500 mg to 1000 mg every 12 to 24 hours
Less than 10	1000 mg initially, then 500 mg to 1000 mg every 24 hours, for *E. coli* and *S. faecalis* 1000 mg every 24 hours
Patients on haemodialysis	1000 mg at the end of dialysis, then 500 mg to 1000 mg every 12 to 24 hours depending on the susceptibility of the organisms involved

Note: the children's dosage is intended for individuals whose weight will not cause dosage to be calculated greater than that recommended for adults. Children weighing more than 20 kg should be dosed according to adult recommendations.

Frequent bacteriological and clinical appraisals are necessary in the treatment of chronic urinary tract infections. Smaller doses than those recommended above should not be used. In stubborn infections, therapy may be required for several weeks. It may be necessary to continue clinical and/or bacteriological follow-up for several months after cessation of therapy.

Treatment should be continued for a minimum of 48 to 72 hours after the patient becomes asymptomatic or evidence of bacterial eradication has been obtained.

To prevent the occurrence of acute rheumatic fever or glomerulonephritis, it is recommended that there be at least ten days treatment for any infection caused by haemolytic Streptococci.

Preparation of Injections

Amoxicillin sodium is unstable in concentrated solutions and, when prepared for injection, should be administered immediately. FISAMOX is for use in one patient on one occasion only and any residue should be discarded.

FISAMOX should be administered immediately following reconstitution, to reduce microbiological hazard. If required, FISAMOX maybe be held under refrigeration (2ºC to 8ºC) for the time periods described in table 3 (see Section 6.4 SPECIAL PRECAUTIONS FOR STORAGE).

1000 mg Vial

- For intramuscular use: add 5.2 mL of water for injections and shake vigorously. Doses larger than 500 mg should be divided between multiple injection sites.

For IV use: dissolve contents in 20 mL of water for injections. Dilutions in excess of 10 mL should be carried out in the syringe. The following table (table 2) may be used as a guide to assist in the preparation of fractional doses of FISAMOX.

Table 2

For concentration of:	100	125	200	250	500	mg per mL
Add:	9.2	7.2	4.2	3.2	1.2	mL Water for Injections

A transient pink colouration or slight opalescence may appear during reconstitution.

If pain is experienced on intramuscular injection, a 0.5% solution of procaine hydrochloride or a 1% solution of lidocaine hydrochloride may be used in place of Water for Injections. For direct intravenous injection, administer by slow injection (at least over a period of 3 to 4 minutes, preferably 10 to 15 minutes). More rapid administration may result in convulsive seizures.

4.3 CONTRAINDICATIONS

Amoxicillin is a penicillin and should not be given to patients with a history of a hypersensitivity to beta-lactam antibiotics (e.g. penicillins, cephalosporins).

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Serious, and occasionally fatal, hypersensitivity reactions (including anaphylaxis, anaphylactoid and severe cutaneous reactions) have been reported in patients receiving beta-lactam antibiotics e.g. penicillins. Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction (see Section 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)). These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and in atopic individuals. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral therapy. Before commencing therapy with any beta-lactam antibiotic, careful enquires should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. If a hypersensitivity reaction occurs, appropriate therapy should be instituted and FISAMOX therapy discontinued.

Serious anaphylactoid reactions require emergency treatment with adrenaline (epinephrine). Oxygen, intravenous steroids and airway management including intubation, should also be administered as indicated.

Drug-induced enterocolitis syndrome (DIES) has been reported mainly in children receiving amoxicillin (see Section 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)). DIES is an allergic reaction with the leading symptom of protracted vomiting (1-4 hours after administration of amoxicillin) in the absence of allergic skin or respiratory symptoms. Further symptoms could comprise abdominal pain, diarrhoea, hypotension or leucocytosis with neutrophilia. There have been severe cases including progression to shock.

Antibiotic associated pseudomembranous colitis has been reported with many antibiotics including amoxicillin. A toxin produced by *Clostridium difficile* appears to be the primary cause. The severity of the

colitis may range from mild to life threatening. It is important to consider this diagnosis in patients who develop diarrhoea or colitis in association with antibiotic use (this may occur up to several weeks after cessation of antibiotic therapy). Mild cases usually respond to drug discontinuation alone. However, in moderate to severe cases, appropriate therapy with a suitable oral antibacterial agent effective against *Clostridium difficile* should be considered. Fluids, electrolyte and protein replacement should be provided when indicated. Drugs which delay peristalsis, e.g. opiates and diphenoxylate with atropine (Lomotil) may prolong and/or worsen the condition and should not be used.

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

Amoxicillin has been found to cause dose-related renal toxicity in laboratory animals when administered daily as a bolus injection at dose levels of 100 mg/kg/day and above. As the metabolic pattern of amoxicillin in humans appears to be similar to that in animals, the possibility of nephrotoxic effect from amoxicillin should be borne in mind.

As with any potent drug, periodic assessment of renal, hepatic and haematopoietic function should be made during prolonged therapy. The possibility of super-infections with mycotic or bacterial pathogens should be kept in mind during therapy. If super-infections occur (usually involving Aerobacter, Pseudomonas or Candida), the drug should be discontinued and/or appropriate therapy instituted.

The possibility of venous irritation when using that route, must be kept in mind.

Caution should be exercised in the treatment of patients with an allergic diathesis. FISAMOX is not the treatment of choice in patients presenting with sore throat or pharyngitis. This is because of the possibility that the underlying cause may be infectious mononucleosis, in the presence of which there is a high incidence of rash if amoxicillin is used. Patients with lymphatic leukaemia also appear to have a higher incidence of skin rashes when treated with amoxicillin.

During treatment with high doses of amoxicillin, particularly by bolus injection, an adequate fluid intake and urinary output must be maintained. In addition, indwelling catheters should be checked regularly for patency since, due to high urinary concentrations, amoxicillin may, at room temperature, precipitate out of solution. The risk of crystalluria should be avoided by maintaining a high urinary output.

The sodium content must be taken into account in patients on a sodium restricted diet if the parenteral administration of high doses is necessary (see Section 6.5 NATURE AND CONTENTS OF CONTAINER).

Use in Renal Impairment

Dosage should be adjusted in severe and moderate renal impairment (see Section 4.2 DOSAGE AND METHOD OF ADMINISTRATION).

Use in the Elderly

No data available

Paediatric Use

No data available

Effects on Laboratory Tests

As administration of FISAMOX will result in high amoxicillin concentrations in the urine, false positive reactions may be elicited when testing the urine for glucose with Clinitest, Benedict's solution or Fehling's solution. Tests based on enzymatic glucose oxidase reactions such as Testape or Clinistix should be used instead.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use with FISAMOX may result in increased and prolonged blood levels of amoxicillin.

Tetracyclines, erythromycin and chloramphenicol antagonise the action of amoxicillin. Gentamicin should not be mixed with amoxicillin when both drugs are given parenterally as inactivation occurs.

The concurrent administration of allopurinol and amoxicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving amoxicillin alone. It is not known whether this potentiation of amoxicillin rashes is due to allopurinol or the hyperuricaemia present in these patients.

In common with other antibiotics, amoxicillin may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral contraceptives. Patients should be warned that FISAMOX may reduce the effectiveness of oral contraceptives.

In the literature there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin.

Methotrexate: Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on Fertility

No data available.

Use in Pregnancy

Pregnancy Category: A

Amoxicillin diffuses across the placenta into the fetal circulation. Animal studies with amoxicillin have shown no teratogenic effects. The product has been in clinical use since 1972 and the limited number of reported cases of use in human pregnancy have shown no evidence of untoward effect.

The use of FISAMOX in pregnancy should be reserved for cases considered essential by the clinician.

Following administration of ampicillin to pregnant women a transient decrease in plasma concentration of total conjugated estriol, estriol-glucuronide, conjugated oestrone and gg has been noted. This effect may also occur with amoxicillin.

Use in Labour and Delivery

Oral ampicillin class antibiotics are generally poorly absorbed during labour. Studies in guinea pigs have shown that intravenous administration of ampicillin decreases uterine tone and the frequency, strength and duration of contractions. However, it is not known whether the use of amoxicillin in humans during labour or delivery has any immediate or delayed adverse effects on the fetus, prolongs the duration of labour or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

Use in Lactation

Amoxicillin is excreted in breast milk. An alternative feeding method is recommended to avoid potential sensitisation of the newborn.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

As with all penicillins, the possibility of hypersensitivity reactions should always be considered. Reactions are more likely to occur in individuals who have previously demonstrated hypersensitivity to penicillins and in those with allergic diathesis. Anaphylactic shock is most likely to occur with injected penicillins (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

The following adverse reactions have been reported as associated with the use of amoxicillin:

Cardiac disorders

Kounis syndrome: not known.

Infections and infestations

Mucocutaneous candidiasis have been reported very rarely.

Gastro-intestinal

Glossitis, stomatitis, black hairy tongue, nausea, vomiting, diarrhoea. Intestinal candidiasis and antibiotic associated colitis (including pseudomembranous colitis and haemorrhagic colitis) have been reported rarely (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

Drug-induced enterocolitis syndrome: not known (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

Skin and subcutaneous tissue disorders

Linear IgA disease: not known.

Hypersensitivity Reactions

Erythematous maculopapular rash, pruritus and urticaria have been reported. Urticaria has occasionally been reported in association with glandular fever and some other viral diseases. Rarely, skin reactions such as erythema multiforme and Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis, acute generalised exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS), and symmetrical drug-related intertriginous and flexural exanthema (SDRIFE) (baboon syndrome) have been reported. As with other antibiotics, severe allergic reactions including angioneurotic oedema, anaphylaxis, serum sickness, hypersensitivity vasculitis and interstitial nephritis have been reported rarely. When such reactions occur, FISAMOX should be discontinued.

Note: Urticaria, other skin rashes, and serum sickness-like reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. Anaphylaxis is the most serious reaction experienced (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE). A macular rash, which is not believed to be a hypersensitivity reaction, occurs predominantly in patients with infectious mononucleosis 4 to 5 days after beginning therapy with amoxicillin.

Hepatic

A moderate rise in AST and/or ALT have occasionally been noted, but the significance of these findings is unknown. As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely.

Renal and Urinary Tract Disorders

Interstitial nephritis, crystalluria (including acute renal injury) (see Section 4.9 OVERDOSE) has been reported rarely.

Haemic and Lymphatic Systems

Anaemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia and leukopenia (including severe neutropenia or agranulocytosis) have been reported during therapy with other penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. Prolongation of bleeding time and prothrombin time have been reported rarely.

Nervous System

Adverse effects have been reported rarely. They include aseptic meningitis, hyperkinesia, dizziness and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses. As the blood brain barrier becomes more permeable in meningitis, toxic symptoms may be precipitated by lower levels of amoxicillin in patients with meningitis.

Other

Vaginal or oral moniliasis may occur following the use of antibiotics.

Ninety percent of all adverse events to amoxicillin recorded in the Australian Adverse Drug Reaction System relate to the skin (rash, pruritus and urticaria).

Injection Site

Pain may be experienced at the site of intramuscular injection and phlebitis at the site of intravenous injection.

Reporting Suspected Adverse Effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and symptoms of water/electrolyte imbalance should be treated. During the administration of high doses of amoxicillin, adequate fluid intake and urinary output must be maintained to minimise the possibility of amoxicillin crystalluria. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

As with other penicillins, amoxicillin in overdosage has the potential to cause neuromuscular hyperirritability or convulsive seizures. As the blood brain barrier becomes more permeable in meningitis, toxic symptoms may be precipitated by lower levels of amoxicillin in patients with meningitis.

Amoxicillin may be removed from the circulation by haemodialysis. General supportive measures should be instituted.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of Action

Amoxicillin has the same spectrum of activity as ampicillin. It is bactericidal and is active against a wider range of Gram-negative organisms than benzylpenicillin. It is less active than benzylpenicillin against Gram-positive organisms but is active in vitro against *Streptococcus pyogenes* and many strains of *Streptococcus pneumoniae*, *Streptococcus viridans*, non-penicillinase producing Staphylococci and *Enterococcus faecalis*. There are strains of *Escherichia coli* that are sensitive to amoxicillin, but isolates are becoming increasingly resistant to amoxicillin *in vitro* due to the presence of penicillinase-producing strains. Many strains of

Haemophilus influenzae, *Neisseria gonorrhoeae*, *Neisseria meningitidis*, *Proteus mirabilis* and *Salmonellae* are sensitive to amoxicillin, although the increasing incidence of beta-lactamase activity in *H. influenzae* and *E. coli* is reducing the capacity of amoxicillin to treat diseases caused by these organisms. Some of the above organisms are sensitive to amoxicillin only at concentrations achieved in the urine.

Amoxicillin is not effective against penicillinase producing bacteria, particularly resistant Staphylococci, which are now common. All strains of Pseudomonas, indole-positive Proteus, *Serratia marcescens*, Enterobacter, Klebsiella and Citrobacter are resistant.

Like benzylpenicillin, amoxicillin is bactericidal to sensitive organisms during the stage of active cell division. It is believed to act through the inhibition of cell wall synthesis.

Susceptibility Tests

Dilution or diffusion techniques – either quantitative (MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (e.g. NCCLS). Standardised susceptibility test procedures require the use of laboratory control microorganisms to control the technique aspects of the laboratory procedures.

A report of "susceptible" indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations achievable. A report of "intermediate" indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone, which prevents small-uncontrolled technical factors from causing major discrepancies in interpretation. A report of "resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable; other therapy should be selected.

Note: the prevalence of resistance may vary geographically for selected species and local information on resistance is desirable, particularly when treating severe infections.

Clinical Trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Following intramuscular injection of 250 or 500 mg of FISAMOX, peak serum levels of approximately 5.5 mg/L or 10 mg/L are achieved within 60 minutes of injection and correspond to the peak values obtained after the same dose given orally. Absorption from the intramuscular site is almost complete.

Following intravenous injection over a 3 to 4 minute period, serum levels at 1 hour were similar to those seen at 1 hour after the same dose given intramuscularly. Serum levels immediately after the IV injection were however, higher. The serum half-life measured as unchanged (active) antibiotic in the excretory phase, is approximately 1 hour in the presence of normal renal function, rising to about 7 hours with a creatinine clearance of 13 mL/minute without dialysis. The elimination half-life does not appear to change until creatinine clearance reaches approximately 30 mL/minute. In patients with a creatinine clearance of 10 mL/minute, elimination half-life has been shown to vary between 7.5 and 21 hours after a 2 g intravenous dose.

Distribution

In keeping with other penicillins, penetration into the CSF is poor in the absence of inflammation. Some penetration occurs though inflamed meninges, but maximum CSF levels are very much lower than peak serum levels.

Bile levels vary with the functional integrity of secretory mechanisms, being absent in the presence of biliary tract obstruction.

Amoxicillin is not highly bound to human serum protein. The degree of binding, as measured by ultrafiltration or equilibrium dialysis, is 17%.

Excretion

The major route of excretion is renal (by glomerular filtration and tubular secretory mechanisms). The secretory mechanisms may be inhibited by the concurrent administration of probenecid, leading to prolonged and some elevation of serum levels.

If renal function is normal, approximately 70% of a dose administered by intramuscular or rapid intravenous injection will be excreted unchanged within six hours, and approximately 20% will be excreted as the penicilloic acid derivative in the same time. In patients with renal failure, renal excretion falls in relation to the glomerular filtration rate, but therapeutic levels are still maintained in the urine.

Results of studies in man, employing thin layer chromatography and bioautography, show that amoxicillin is not changed *in vivo* into substances with antibacterial activity.

There appears to be only one metabolic breakdown product, namely, penicilloic acid.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

The powder for injection contains no excipients.

6.2 INCOMPATIBILITIES

FISAMOX is compatible with commonly used intravenous solutions (see Section 6.4 SPECIAL PRECAUTIONS FOR STORAGE). However, it should not be mixed with blood products or proteinaceous fluids such as protein hydrolysates, nor with intravenous lipid emulsions.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Dry powder: store below 25°C.
Protect from light and moisture.

Solutions: when prepared for intramuscular or direct intravenous injection, FISAMOX should be administered immediately after reconstitution.

Intravenous fluids: infusions should be administered over a period of 30 to 60 minutes although FISAMOX maintains a satisfactory degree of activity at room temperature in various infusion fluids.

If the solutions listed below are stored under refrigeration (2°C to 8°C), they will remain stable for the time periods indicated (see Table 3).

Table 3: Storage of Intravenous Fluids at 2ºC to 8ºC

Intravenous Solution	Concentration	Stability Period
Water for injections	30 mg/mL	24 hours
Water for injections	up to 20 mg/mL	48 hours
Isotonic sodium chloride solution	30 mg/mL	8 hours
Isotonic sodium chloride solution	up to 10 mg/mL	72 hours
Lactated Ringer's solution	up to 20 mg/mL	24 hours
M/6 sodium lactate solution	up to 30 mg/mL	8 hours
5% glucose in water	up to 20 mg/mL	4 hours
5% glucose in 0.45% sodium chloride solution	up to 30 mg/mL	4 hours
10% invert syrup in water	up to 30 mg/mL	2 hours
5% glucose, 5% ethanol in water	up to 20 mg/mL	8 hours
5% glucose, 5% ethanol in water	20 to 30 mg/mL	4 hours

Since FISAMOX is relatively less stable in carbohydrate solutions, it is preferable to avoid adding it to them. However, it may be injected into the drip tubing of such an infusion or incorporated into a small volume of the solution and infused over a period of 30 to 60 minutes.

As there is some loss of potency during storage at 2ºC to 8°C, solutions that have been stored at 2ºC to 8°C for periods within the limits stated above, should be used immediately once they have been brought to room temperature.

6.5 NATURE AND CONTENTS OF CONTAINER

Each one gram of monograph substance represents about 2.6 mmol of sodium (59.8 mg of sodium).

Container type: vial (glass type II clear)

Pack sizes: 5, 10

Some strengths, pack sizes and/or pack types may not be marketed.

Australian Register of Therapeutic Goods (ARTG)

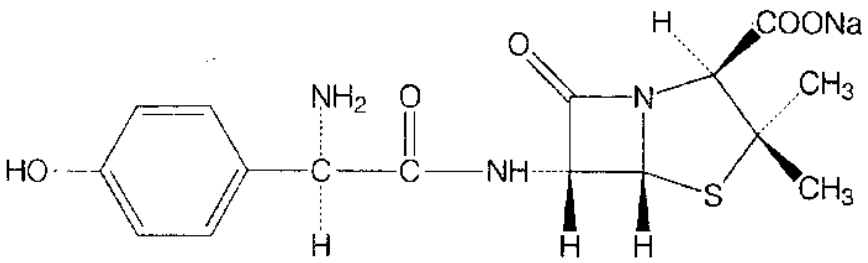
AUST R 90880 – FISAMOX amoxicillin (as sodium) 1000 mg powder for injection vial

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking it to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical Structure



FISAMOX is a fine white to off-white homogenous powder, soluble in water.

Chemical name: d-(-)-α-amino-p-hydroxybenzyl penicillin sodium.

Molecular formula: $C_{16}H_{18}N_3NaO_5S$

Molecular weight: 387.4

CAS Number

34642-77-8

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 (Prescription Only Medicine)

8 SPONSOR

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9 DATE OF FIRST APPROVAL

1000 mg: 28/11/2002

10 DATE OF REVISION

18/12/2024

Summary Table of Changes

Section Changed	Summary of New Information
All	Minor editorial changes
4.4	Expanded warnings on hypersensitivity reactions. Included drug-induced enterocolitis syndrome.
4.5	Included methotrexate and additional warning on probenecid.
4.8	Included mucocutaneous candidiasis, Linear IgA disease, Kounis syndrome, drug-induced enterocolitis syndrome, acute renal injury, aseptic meningitis, symmetrical drug-related intertriginous and flexural exanthema (SDRIFE) (baboon syndrome).

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