New Zealand Data Sheet

1. PRODUCT NAME

Ibiamox® 250 mg Powder for injection
Ibiamox® 500 mg Powder for injection
Ibiamox® 1000 mg Powder for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The amoxicillin is present as the sodium salt in Ibiamox (1059 mg of amoxicillin sodium is equivalent to approximately 1000mg of amoxicillin).
Ibiamox 250 mg Powder for injection contains 250 mg amoxicillin.
Ibiamox 500 mg Powder for injection contains 500 mg amoxicillin.
Ibiamox 1000 mg Powder for injection contains 1000 mg amoxicillin.

3. PHARMACEUTICAL FORM

Ibiamox vials: white to cream powder packed in clear glass vials for reconstitution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Amoxicillin should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data.

Amoxicillin is indicated for treatment of infections in adults and children at the following sites, when caused by sensitive organisms:

- upper respiratory tract including ear, nose and throat infections, e.g., tonsillitis, sinusitis, otitis media
- lower respiratory tract, e.g., acute exacerbations of chronic bronchitis, lobar and bronchopneumonia
- gastrointestinal tract, e.g., typhoid fever
- genito-urinary tract, e.g., cystitis, urethritis, pyelonephritis, bacteriuria in pregnancy, gonorrhoea, septic abortion, puerperal sepsis
- other infections including Borreliosis (Borrelia burgdorferi) (Lyme Disease)
- prophylaxis of endocarditis: amoxicillin may be used for the prevention of bacteraemia associated with the development of endocarditis (see table in section 4.2 Dose and method of administration)
- Skin and soft tissue infections (SSTIs).

Susceptibility to amoxicillin will vary with geography and time and local susceptibility data should be consulted where available and microbiological sampling and susceptibility testing performed where necessary (see section 5.1).

4.2. Dose and method of administration

Dose

Parenteral therapy is indicated if the oral route is considered impracticable or unsuitable, as in the case of severe diarrhoea or vomiting, and particularly for the urgent treatment of severe infection.

Therapy can be started parenterally and continued with oral amoxicillin.

Amoxicillin may be administered either by slow intravenous injection over a period of 3 to 4 minutes directly into a vein or via a drip tube or by infusion over 30 to 60 minutes.

Amoxicillin doses should not be given at intervals of less than 4 hourly.

Treatment should be continued for 48 to 72 hours beyond the time that a clinical response has been obtained.

It is recommended that at least ten days treatment be given for any infection caused by beta-haemolytic streptococci to eradicate the infecting organism and prevent the occurrence of acute rheumatic fever or glomerulonephritis.

Although amoxicillin possesses the characteristic low toxicity of the penicillin group of antibiotics, periodic assessment of organ system function, including renal, hepatic and haematopoietic functions, is advisable during prolonged therapy.

Adults and children ≥ 40 kg

Intravenous:

Usual daily dosage of 750 mg to 6 g administered in divided doses.
Maximum recommended daily dosage: 12 g/day.
Maximum single dose: 2 g by infusion or 1 g by bolus injection.
Lyme disease: 4 g/day in isolated erythema chronicum migrans and 6 g/day in the case of generalised manifestations, both for a minimum of 12 days.

Intramuscular:

Maximum recommended daily dosage: 4 g/day.
Maximum single dose: 1 g.

Children < 40 kg

Intravenous:

Usual daily dose of 20 to 200 mg/kg/day in divided doses.

Maximum daily dosage:

Premature (up to 4 kg)	100 mg/kg/day given as 2 equally divided doses by 12 hourly infusions.
Greater than 4 kg up to 3 months	150 mg/kg/day given as 3 equally divided doses by 8 hourly infusions.
3 months to 12 years	200 mg/kg/day given in 2 to 4 equally divided doses of up to 25 mg/kg or infusions of up to 50 mg/kg.

Maximum single dose: 50 mg/kg.
Lyme disease: 25 to 50 mg/kg/day in isolated erythema chronicum migrans and 100 mg/kg/day in the case of generalised manifestations, both for a minimum of 12 days.

Intramuscular:

Maximum daily dosage: 120 mg/kg/day as 2 to 6 equally divided doses.

Prophylaxis of Endocarditis- intravenous

Consideration should be given to official guidelines and/or hospital and dental formularies.

Condition		**Adults and children ≥ 40 kg**	**Children < 40 kg**
Dental Procedures: In patients with the highest risk of infective endocarditis that require manipulation of the gingival or periapical region of the teeth, or perforation of the oral mucosa.	**Patients having general anaesthetic:** oral antibiotics not appropriate.	2 g as a single intravenous dose 30-60 minutes before procedure.	50 mg/kg as a single intravenous dose 30-60 minutes before procedure.

Special populations

Renal impairment

	Adults and children ≥ 40 kg		**Children < 40 kg**	
GFR (mL/min)	**Intravenous**	**Intramuscular**	**Intravenous**	**Intramuscular**
greater than 30	No adjustment	No adjustment	No adjustment	No adjustment
10 to 30	1 g stat, then 500 mg to 1 g twice day	500 mg every 12 hours	25 mg/kg twice daily	15 mg/kg every 12 hours
less than 10	1 g stat, then 500 mg/day	500 mg/day given as a single dose	25 mg/kg/day given as a single dose	15 mg/kg/day given as a single dose

In patients receiving haemodialysis and peritoneal dialysis

Amoxicillin may be removed from the circulation by haemodialysis.

	Haemodialysis		**Peritoneal dialysis**	
	Intravenous	**Intramuscular**	**Intravenous**	**Intramuscular**
Adults and children ≥ 40 kg	1 g at the end of dialysis, then 500 mg every 24 hours	500 mg during dialysis, 500 mg at the end, then 500 mg every 24 hours	1 g stat, then 500 mg/day	500 mg/day given as a single dose
Children < 40 kg	25 mg/kg stat and 12.5 mg/kg at the end of the	15 mg/kg during and at the end of dialysis, then 15	25 mg/kg/day given as a single dose	15 mg/kg/day given as a single dose

	dialysis, then 25 mg/kg/day	mg/kg every 24 hours		

Method of Administration

Intravenous

Ibiamox may be administered either by slow intravenous injection over a period of 3 to 4 minutes or via infusion over a period of 30 to 60 minutes.

Intramuscular

Ibiamox is administered as a bolus dose.

For instructions on reconstitution and preparation before administration, see section 6.6.

4.3. Contraindications

Amoxicillin is contraindicated in patients with a hypersensitivity to the active substance, beta-lactam antibiotics.

4.4. Special warnings and precautions for use

Hypersensitivity reactions

Amoxicillin should be given with caution to patients who have experienced symptoms of allergy associated with a cephalosporin or penicillin. Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy.

Before commencing therapy with any penicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, cephamycins or penicillamine (see sections 4.3 and 4.8). Caution should also be taken in patients with a history of allergy, such as eczema, asthma, hay fever and hives. If any allergic reaction occurs, appropriate therapy should be instituted and amoxicillin therapy should be discontinued.

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and in atopic patients (see section 4.3). If an allergic reaction occurs, amoxicillin therapy must be discontinued and appropriate alternative therapy instituted. Serious anaphylactic reactions may require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management, including intubation, may also be required. Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction (see section 4.8).

Serious anaphylactoid reactions require emergency treatment with adrenaline, oxygen and intravenous steroids. Airway management including tubation should also be administered as indicated.

Drug-induced enterocolitis syndrome (DIES)

Drug-induced enterocolitis syndrome (DIES) has been reported mainly in children receiving amoxicillin (see section 4.8). DIES is an allergic reaction with the leading symptom of protracted

vomiting (1-4 hours after taking the medicine) 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.

Electrolytes

Massive doses of amoxicillin can cause hypokalaemia and sometimes hypernatraemia. Use of a potassium-sparing diuretic may be helpful. In patients undergoing high-dose treatment for more than 5 days, electrolyte balance, blood counts and renal functions should be monitored.

The sodium content must be taken into account in patients on a sodium restricted diet if the parenteral administration of high doses is necessary. Each 1 g vial of amoxicillin contains 3.3 mmol of sodium.

Pseudomembranous colitis

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It is important to consider this diagnosis in patients who develop severe and persistent diarrhoea during or after receiving amoxicillin. In this situation, even if *Clostridium difficile* is only suspected, administration of amoxicillin should be discontinued and appropriate treatment given.

Prolonged therapy

Periodic assessment of renal, hepatic and haematopoietic function should be made during prolonged therapy. Prolonged use may occasionally result in overgrowth of non-susceptible organisms. The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving aerobacter, pseudomonas or candida), the medicine should be discontinued and/or appropriate therapy instituted.

Convulsions

Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Anticoagulants

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 concomitantly. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation (see sections 4.5 and 4.8).

Crystalluria

In patients with reduced urine output (including acute renal injury), crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria . In patients with bladder catheters, a regular check of patency should be maintained (see sections 4.5, 4.8 and 4.9).

Skin reactions

The occurrence at the treatment initiation of a feverish generalised erythema associated with pustula may be a symptom of acute generalised exanthemous pustulosis (see section 4.8).

Amoxicillin should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin. Amoxicillin should be given with caution to patients with infectious mononucleosis or lymphatic leukemia since they are especially susceptible to ampicillin induced skin rashes.

Other reactions that may rarely occur include drug reaction with eosinophilia and systemic symptoms (DRESS) and symmetrical drug-related intertriginous and flexural exanthema (SDRIFE) (baboon syndrome)

Jarisch-Herxheimer reaction

The Jarisch-Herxheimer reaction has been seen following amoxicillin treatment of Lyme disease (see section 4.8). It results directly from the bactericidal activity of amoxicillin on the causative bacteria of Lyme disease, the spirochaete Borrelia burgdorferi. Patients should be reassured that this is a common and usually self-limiting consequence of antibiotic treatment of Lyme disease.

4.5. Interaction with other medicines and other forms of interaction

Probenecid

Probenecid decreases renal tubular secretion of penicillins when used concurrently, resulting in increased and more prolonged amoxicillin serum concentrations and prolonged elimination half-life.

Allopurinol

There has been a report of an increased incidence of skin rash on concurrent administration.

Oral Anticoagulants

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 concomitantly. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation (see sections 4.4 and 4.8).

Bacteriostatic Antibiotics

Since bacteriostatic agents such as chloramphenicol, erythromycin, sulfonamides or tetracyclines may interfere with the bactericidal effect of penicillins in the treatment of meningitis or other situations where a rapid bactericidal effect is necessary, it is best to avoid concurrent therapy.

Methotrexate

Penicillins reduce the excretion of methotrexate thereby increasing the risk of methotrexate toxicity.

Interference with diagnostic tests

Penicillins may interfere with:

- Urinary glucose test – it is recommended that when testing for the presence of glucose in urine during amoxicillin treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of amoxicillin, false positive readings are common with chemical methods.
- Coomb's tests- interferes with positive direct antiglobulin

- Tests for urinary or serum proteins
- Tests which use bacteria e.g., Guthrie test
- Liver enzymes- serum alanine aminotransferase (ALT) and serum aspartate aminotransferase (AST) concentrations may be increased
- Total conjugated estriol, estriol-glucuronide, conjugated estrone and estradiol concentrations may be transiently decreased following amoxicillin administration to pregnant women.

Oestrogen Containing Oral Contraceptives

In common with other antibiotics, amoxicillin may affect the gut flora, leading to lower oestrogen reabsorption, therefore concurrent administration with amoxicillin may decrease the effectiveness of oral contraceptives. Patients should be advised to use an alternative or additional method of contraception.

4.6. Fertility, pregnancy and lactation

Pregnancy

Safety for use in pregnancy has not been established. Reproduction studies have been performed in mice and rats at doses of up to 10 times the human dose and these studies have revealed no evidence of impaired fertility or harm to the foetus due to amoxicillin. Amoxicillin is known to diffuse across the placenta. Amoxicillin may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

Breast-feeding

Trace quantities of penicillin can be detected in breast milk with the potential for hypersensitivity reactions (e.g., drug rashes) or gastrointestinal disorders (e.g. diarrhoea or candidiasis) in the breast-fed infant. Consequently, breastfeeding might have to be discontinued.

Fertility

There are no data on the effects of amoxicillin on fertility in humans. Reproductive studies in animals have shown no effects on fertility.

4.7. Effects on ability to drive and use machines

During treatment with Ibiamox, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions) which may influence the ability to drive and use machines. Patients should be cautious when driving or operating machinery (see section 4.8).

4.8. Undesirable effects

The following convention has been utilised for the classification of undesirable effects:
Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)

The majority of the side-effects listed below are not unique to amoxicillin and may occur when using other penicillins.

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

Blood and Lymphatic System Disorders	
Very rare	Reversible leucopenia (including severe neutropenia or agranulocytosis), reversible thrombocytopenia and haemolytic anaemia. Prolongation of bleeding time and prothrombin time (see section 4.4).
Cardiac disorders	
Very rare	Kounis syndrome
Immune system disorders	
Very rare	As with other antibiotics, severe allergic reactions, including angioneurotic oedema, anaphylaxis (see section 4.4), serum sickness and hypersensitivity vasculitis.
Not known	Jarish-Herxheimer reaction
If a hypersensitivity reaction is reported, the treatment must be discontinued (see skin and subcutaneous tissue disorders).	
Nervous system disorders	
Very rare	Hyperkinesia, dizziness and convulsions (see section 4.4). Aseptic meningitis
Infections and Infestations	
Very rare	Mucocutaneous candidiasis.
Gastrointestinal disorders	
#Common	Diarrhoea and nausea.
#Uncommon	Vomiting.
Very rare	Antibiotic associated colitis (including pseudomembraneous colitis and haemorrhagic colitis – see section 4.4). Black hairy tongue. Superficial tooth discolouration.^
Not known	Drug-induced enterocolitis syndrome (DIES)
Hepato-biliary disorders	
Very rare	Hepatitis and cholestatic jaundice. A moderate rise in AST and/or ALT. The significance of a rise in AST and/or ALT is unclear.
Skin and subcutaneous tissue disorders	
#Common	Skin rash.
#Uncommon	Urticaria and pruritus.
Very rare	Skin reactions such as erythema multiforme, Stevens- Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis and acute generalised exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS.)
Not known	Linear IgA disease, Symmetrical drug-related intertriginous and flexural exanthema (SDRIFE) (baboon syndrome) (See also immune system disorders).
Renal and Urinary tract disorders	
Very rare	Interstitial nephritis, crystalluria (including acute renal injury) (see sections 4.4 and 4.9)
# The incidence of these AEs was derived from clinical studies involving a total of approximately 6,000 adult and paediatric patients taking amoxicillin. ^ Superficial tooth discolouration has been reported in children. Good oral hygiene may help to prevent tooth discolouration as it can be removed by brushing.	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected reactions https://pophealth.my.site.com/carmreportnz/s/

4.9. Overdose

Symptoms

Gastrointestinal symptoms (such as nausea, vomiting and diarrhoea) leading to a disturbance of fluid and electrolyte balance may be evident. Problems are unlikely if adequate fluid is maintained but crystalluria, in some cases leading to renal failure, has been observed (see section 4.4). Convulsions may occur in patients with impaired renal function or in those receiving high doses (see sections 4.4 and 4.8). Obvious overdose will produce very high urinary concentrations, particularly after parenteral administration.

Amoxicillin has been reported to precipitate in bladder catheters after intravenous administration of large doses. A regular check of patency should be maintained.

Treatment

Gastrointestinal symptoms may be treated symptomatically, with attention to the water/electrolyte balance. Amoxicillin may be removed by haemodialysis.

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic Group: Beta-lactam antibacterials, penicillins with extended spectrum ATC code: J01CA04

Mechanism of action

Amoxicillin is a semi-synthetic aminopenicillin of the beta-lactam group of antibiotics. It has a broad spectrum of antibacterial activity against many Gram-positive and Gram-negative micro-organisms, acting through the inhibition of biosynthesis of cell wall mucopeptide. Amoxicillin is, however, susceptible to degradation by beta-lactamases and therefore the spectrum of activity does not include organisms which produce these enzymes including resistant staphylococci, and all strains of *Pseudomonas*, *Klebsiella* and *Enterobacter.*

Pharmacodynamic Effects

The prevalence of acquired resistance is geographically and time dependant and for select species may be very high. Local information on resistance is desirable, particularly when treating severe infections.

In vitro susceptibility of micro-organisms to amoxicillin
Where clinical efficacy of amoxicillin has been demonstrated in clinical trials this is indicated with an asterisk (*).
†Natural intermediate susceptibility in the absence of acquired mechanism of resistance.

Commonly Susceptible Species
Gram-positive aerobes: *Bacillus anthracis* *Enterococcus faecalis** *Beta-hemolytic streptococci** *Listeria monocytogenes*
Gram-negative aerobes: *Bordetella pertussis*
Other: *Leptospira icterohaemorrhagiae* *Treponema pallidum*
Species for which acquired resistance may be a problem
Gram-negative aerobes: *Escherichia coli** *Haemophilus influenzae** *Helicobacter pylori** *Proteus mirabilis** *Salmonella spp.* *Shigella spp.* *Neisseria gonorrhoeae** *Pasteurella spp.* *Vibrio cholerae*
Gram-positive aerobes: *Coagulase negative staphylococcus** *Corynebacterium spp.* *Staphylococcus aureus ** *Streptococcus pneumoniae** *Viridans group streptococcus**
Gram-positive anaerobes: *Clostridium spp.*
Gram-negative anaerobes: *Fusobacterium spp.*
Other: *Borrelia burgdorferi*
Inherently resistant organisms
Gram-positive aerobes: *Enterococcus faecium†*
Gram-negative aerobes: *Acinetobacter spp.* *Enterobacter spp.* *Klebsiella spp.* *Pseudomonas spp.*
Gram-negative anaerobes: *Bacteroides spp*. (many strains of *Bacteroides fragilis* are resistant).
Others: *Chlamydia spp.* *Mycoplasma spp.* *Legionella spp.*

5.2. Pharmacokinetic properties

Absorption

Amoxicillin is well absorbed after intra-muscular administration of any of the injection potencies, the relative bioavailability versus intravenous injection ranging from 73.2 – 96.7%.

Distribution

Amoxicillin is widely distributed to most body tissues and fluids. It penetrates well into purulent and mucoid sputum and into the middle ear. Penetration into cells, the eye and the cerebral spinal fluid is poor. However, inflammation of the meninges increases the amount of amoxicillin that crosses the blood brain barrier.

Amoxicillin is not highly protein-bound, being only 18% protein-bound in serum.

Metabolism

Small amount of amoxicillin is metabolised by hydrolysis to the inactive penicilloic acid, which is partly excreted in the urine.

Elimination

The half-life of amoxicillin is 61.3 minutes with normal renal function. About 75% of a 1 g dose is excreted in the urine in 6 hours in the presence of normal renal function. 60% of this is unchanged and is excreted by glomerular filtration and tubular secretion, while 15% is amoxicillin's inactive metabolite (penicilloic acid). The amount of amoxicillin found in the bile is variable depending on normal biliary secretory function.

Age

The elimination half-life of Ibiamox is prolonged in neonates and the elderly due to incomplete or decreased renal function.

Renal impairment

In renal impairment the excretion of the antibiotic will be delayed (see section 4.2).

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

None

6.2. Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

Ibiamox should not be mixed with blood products, other proteinaceous fluids such as protein hydrolysates or with intravenous lipid emulsions.

If prescribed concomitantly with an aminoglycoside (such as gentamicin), the antibiotics should not be mixed in the same syringe or intravenous fluid container due to loss of activity of the aminoglycoside under these conditions.

6.3. Shelf life

36 months

6.4. Special precautions for storage

Store at or below 25°C

Protect from moisture and light.

When prepared for intramuscular or direct intravenous injection, Ibiamox should be administered immediately or within 1 hour after reconstitution. When prepared for infusions, Ibiamox should be administered within 1 hour, even though Ibiamox maintains a satisfactory degree of activity at room temperature in various infusion fluids see section 6.6.

6.5. Nature and contents of container

Ibiamox 250 mg or 500 mg or 1000 mg injections are in glass vials in pack sizes of 1 vial or 10 vials. Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

Reconstitution of vials

Solutions should be thoroughly mixed by vigorous shaking and checked for absence of particulate matter before use.

Route of administration

Intramuscular injection

Reconstitute with water for injections. Shake immediately after adding the diluent. Add 2 mL to 250 mg and 500 mg vials and 4 mL to a 1 g vial and inject the total volume produced. A transient pink colouration or slight opalescence may appear during reconstitution. Reconstituted solutions are normally a pale straw colour. If pain is experienced on intramuscular injection, a sterile 1% solution of lignocaine hydrochloride or 0.5% solution of procaine hydrochloride may be used in place of water for injections. When giving part doses refer to the section on reconstitution of part doses.

Intravenous injection

Reconstitute with 5 mL of water for injection and shake immediately after adding the diluent by slow injection (over 3- 4 minutes) into the injection site of the giving set of infusions listed below.

Infusion fluids compatible with amoxicillin sodium

When prepared for infusions, Ibiamox should be administered within 1 hour, even though Ibiamox maintains a satisfactory degree of activity at room temperature in various infusion fluids as follows:

Intravenous Fluids	Stability Time
Sodium chloride injection (Normal saline)	6 hours
Compound sodium chloride injection (Ringer's solution)	6 hours
Sodium lactate injection	3 hours
Compound sodium lactate injection (Hartmann's solution)	3 hours
Dextrose injection (5%)	1 hour
Sodium chloride and (4%) dextrose injection	1 hour

Since Ibiamox injection is relatively less stable in carbohydrate solutions, it is preferable to avoid using them. It may, however, 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. Ibiamox injection is compatible with commonly used intravenous solutions.

It should not be mixed with blood products or proteinaceous fluids such as protein hydrolysates, nor with intravenous lipid emulsions.

Reconstitution of part doses

The dry powder in the vial displaces a set volume once it is in solution, therefore this must be allowed for by calculating the volume of diluent to be added to ensure the correct dose is given.

250 mg of stated activity displaces 0.2 mL of diluent.
500 mg of stated activity displaces 0.4 mL of diluent.
1000 mg of stated activity displaces 0.8 mL of diluent.

For example: Add 4.8 mL of diluent to a 250 mg vial to produce:
250 mg in 5 mL, 200 mg in 4 mL, 150 mg in 3 mL, 100mg in 2 mL, 50 mg in 1 mL.
Similarly, add 4.6mL of diluent to a 500mg vial to produce 500 mg in 5 mL solution.
When the whole vial dose is to be given either add 5 mL and withdraw and administer the entire contents or calculate the displacement and add a lesser volume of 5 mL. Solutions should be thoroughly mixed by vigorous shaking and checked for absence of particulate matter before use.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

Douglas Pharmaceuticals Ltd
P O Box 45 027
Auckland 0651
New Zealand
Phone: (09) 835 0660

9. DATE OF FIRST APPROVAL

09 December 1982

10. DATE OF REVISION OF THE TEXT

29 September 2025

Summary table of changes

Section changed	Summary of new information
4.4	Added: Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and in atopic patients (see section 4.3). If an allergic reaction occurs, amoxicillin therapy must be discontinued and appropriate alternative therapy instituted. Serious anaphylactic reactions may require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management, including intubation, may also be required. Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction (see section 4.8). **Drug-induced enterocolitis syndrome (DIES)** Drug-induced enterocolitis syndrome (DIES) has been reported mainly in children receiving amoxicillin (see section 4.8). DIES is an allergic reaction with the leading symptom of protracted vomiting (1-4 hours after taking the medicine) 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. **Jarisch-Herxheimer reaction** The Jarisch-Herxheimer reaction has been seen following amoxicillin treatment of Lyme disease (see section 4.8). It results directly from the bactericidal activity of amoxicillin on the causative bacteria of Lyme disease, the spirochaete Borrelia burgdorferi. Patients should be reassured that this is a common and usually self-limiting consequence of antibiotic treatment of Lyme disease. Updated section on crystalluria to: In patients with reduced urine output (including acute renal injury), crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria . In patients with bladder catheters, a regular check of patency should be maintained (see sections 4.5, 4.8 and 4.9).
4.8	Added: Cardiac disorders: Kounis syndrome-Very rare Under Immune system disorders: Jarish-Herxheimer reaction-Not known. Under Gastrointestinal disorders: Black hairy tongue-very rare, Superficial tooth discolouration-very rare (with footnote explanation) and Drug-induced enterocolitis syndrome (DIES)-Not known. Under skin and subcutaneous tissue disorders, added Linear IgA disease and re-classified Symmetrical drug-related intertriginous and

	flexural exanthema (SDRIFE) (baboon syndrome) (See also immune system disorders) under “Not known” Under renal and urinary disorders, updated to: Interstitial nephritis, crystalluria (including acute renal injury) (see sections 4.4 and 4.9)
4.9	Replaced: “For advice” with: “For risk assessment and advice”