Public Summary

Summary for ARTG Entry: 92765 IBIAMOX amoxicillin 1g (as sodium) powder for injection vial

ARTG entry for	Medicine Registered
Sponsor	Juno Pharmaceuticals Pty Ltd
Postal Address	Level 2 6 Bond Street, South Yarra, VIC, 3141 Australia
ARTG Start Date	21/02/2003
Product category	Medicine
Status	Active
Approval area	Drug Safety Evaluation Branch

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. IBIAMOX amoxicillin 1g (as sodium) powder for injection vial

Product Type Single Medicine Product **Effective date** 6/11/2015

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

IBIAMOX is intended for use where the patient's condition precludes the administration of the oral form of amoxycillin. It is indicated for the treatment of the following infections due to susceptible strains of sensitive organisms: Septicaemia: (bacterial) H. influenzae; E. coli (see Microbiology); P. mirabilis; Streptococcus; S. pneumoniae; S. faecalis and Salmonella typhi. Skin and Skin structure: staphylococcus, non-penicillinase-producing; streptococcus; E. coli (see Microbiology). Respiratory, Acute and Chronic: Haemophilus influenzae; streptococcus; S. pneumoniae; staphylococcus, non-penicillinase producing; E. coli (see Microbiology). Genitourinary Tract (complicated and uncomplicated), Acute and Chronic: E. coli (see Microbiology); P. mirabilis and S. faecalis. Gonorrhoea: N.gonorrhoea (non-penicillinase producing). Prophylaxis of endocarditis: Amoxycillin sodium 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. Note: Therapy should be guided by bacteriological studies, including sensitivity tests, and clinical response. However, in emergency cases where the causative organism has not been identified, therapy with amoxycillin sodium may be useful. Clinical judgement will decide whether combination with another antibiotic would provide a sufficiently broad spectrum of activity pending sensitivity test results.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Not recorded	3 Years	Store below 25 degrees Celsius	Not recorded	Protect from Light Protect from Moisture

Pack Size/Poison information

Pack Size	Poison Schedule
10	(S4) Prescription Only Medicine
1 x 5 vials	(S4) Prescription Only Medicine

Components

1. Medicine Component

Dosage Form	Injection, powder for
Route of Administration	Intravenous Intramuscular

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Visual Identification	CLEAR GLASS VIALS CONTAINING A WHITE OR ALMOST WHITE POWDER

Active Ingredients	
amoxicillin	**1 g**

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