Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	269162	AMOXICLAV JUNO 500/100 amoxicillin (as sodium) 500 mg and clavulanic acid (as potassium clavulanate) 100mg 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	18/01/2017
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. AMOXICLAV JUNO 500/100 amoxicillin (as sodium) 500 mg and clavulanic acid (as potassium clavulanate) 100mg powder for injection vial

Product Type	Single Medicine Product	**Effective date**	11/09/2017

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

AMOXICLAV JUNO is an antibiotic alternative to narrow spectrum and broad-spectrum antibiotics for the treatment of polymicrobial infections; especially in mixed Gram negative and Gram positive infections, and situations where microbial confirmation has not yet been obtained.
Infections caused by amoxicillin susceptible organisms are amenable to AMOXICLAV JUNO treatment due to its amoxicillin content. Infections caused by ?-lactamase producing amoxicillin resistant organisms are also amenable to AMOXICLAV JUNO due to its clavulanic acid content.
Susceptibility to AMOXICLAV JUNO will vary with geography and time. Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary. Amoxicillin/clavulanic acid should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data.
AMOXICLAV JUNO is indicated for the short term treatment of serious bacterial infections such as:
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· Upper Respiratory Tract Infections (including ENT): e.g. mastoiditis, tonsillitis, otitis media, epiglotitis and sinusitis when accompanied by severe signs and symptoms
· Lower Respiratory Tract Infections: e.g. acute exacerbations of chronic bronchitis, lobar, broncho-pneumonia and community acquired pneumonia
· Genito-urinary Tract Infections: e.g. cystitis, urethritis, pyelonephritis, , female genital infections
· Gastrointestinal infections - e.g. intra-abdominal sepsis, peritonitis.
· Skin and skin structure infections, in particular cellulitis, animal bites, diabetic foot infections, vascular surgery infection/ischaemic soft tissue infection, severe dental abscess
· Other Infections e.g. septic abortion, puerperal sepsis, post-surgical infections.
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· AMOXICLAV JUNO is indicated for prophylaxis against infection in major surgical procedures that may be associated with higher risk of infectious complications eg. gastronitestinal surgery.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type III Clear	2 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

1	(S4) Prescription Only Medicine
50	(S4) Prescription Only Medicine
20	(S4) Prescription Only Medicine
10	(S4) Prescription Only Medicine
5	(S4) Prescription Only Medicine

Components

1. AMOXICLAV JUNO 500/100 amoxicillin (as sodium) 500 mg and clavulanic acid (as potassium clavulanate) 100mg powder for injection vial

Dosage Form	Injection, powder for
Route of Administration	Intravenous
Visual Identification	white to off-white sterile powder

Active Ingredients

amoxicillin sodium	**530.1 mg**
potassium clavulanate	**119.13 mg**

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