



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 92841 FLUBICLOX flucloxacillin (as sodium) 500 mg 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 14/02/2003
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. FLUBICLOX flucloxacillin (as sodium) 500 mg powder for injection vial

Product Type	Single Medicine Product	Effective date	1/11/2017
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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

Treatment of confirmed or suspected staphylococcal infections and other Gram-positive coccal infections including pneumonia, skin and skin structure and wound infections, infected burns and cellulitis.

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 Moisture Protect from Light

Pack Size/Poison information

Pack Size

1 x 5 vials
 10 vials

Poison Schedule

(S4) Prescription Only Medicine
 (S4) Prescription Only Medicine

Components

1. FLUBICLOX flucloxacillin (as sodium) 500 mg powder for injection vial

Dosage Form

Injection, powder for

Route of Administration

Intraarticular
 Intrapleural
 Intramuscular
 Intravenous

Visual Identification

CLEAR GLASS VIALS CONTAINING A WHITE TO OFF-WHITE POWDER.

Active Ingredients

Public Summary



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Flucloxacillin

500 mg

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