



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	162744	DICLOXSIG dicloxacillin (as sodium) 250mg capsule bottle
ARTG entry for	Medicine Registered	
Sponsor	Aspen Pharmacare Australia Pty Ltd	
Postal Address	34-36 Chandos Street, ST LEONARDS, NSW, 2065 Australia	
ARTG Start Date	7/09/2009	
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 . DICLOXSIG dicloxacillin (as sodium) 250mg capsule bottle

Product Type	Single Medicine Product	Effective Date	19/02/2021
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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

Dicloxsig is indicated in the treatment of confirmed or suspected staphylococcal and other Gram positive coccal infections, including skin and skin structure and wound infections, infected burns, cellulitis, osteomyelitis and pneumonia. Note: Benzylpenicillin is the drug of choice for the treatment of streptococcal pneumonia. Bacteriological studies should be performed to determine the causative organisms and their susceptibility to dicloxacillin. Dicloxsig should not be used in infections due to organisms susceptible to benzylpenicillin. Important Note: When it is judged necessary that the treatment be initiated before definitive culture and sensitivity results are known, if the microbiology report later indicates the infection is due to an organism other than a benzylpenicillin resistant staphylococcus sensitive to dicloxacillin, the physician is advised to continue therapy with a drug other than dicloxacillin or any other penicillinase resistant penicillin.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Glass Type I Coloured	1 Years	Store below 25 degrees Celsius	Not recorded	Protect from Moisture

Pack Size/Poison information

Pack Size	Poison Schedule
24 capsules	(S4) Prescription Only Medicine

Components

1 . Medicine Component

Dosage Form	Capsule
Route of Administration	Oral
Visual Identification	Size 1 hard gelatin capsule with white body and cap.

Active Ingredients

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dicloxacillin sodium	271.26 mg
Equivalent: dicloxacillin	250 mg

Other Ingredients (Excipients)

Gelatin
magnesium stearate
silicon dioxide
titanium dioxide

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