



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	114044	CIROFAXIN ciprofloxacin 500mg (as hydrochloride monohydrate) tablet blister pack
ARTG entry for	Medicine Registered	
Sponsor	Strides Pharma Science Pty Ltd	
Postal Address	5/148-152 Spit Road, Mosman, NSW, 2088 Australia	
ARTG Start Date	5/11/2004	
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 . CIROFAXIN ciprofloxacin 500mg (as hydrochloride monohydrate) tablet blister pack

Product Type	Single Medicine Product	Effective Date	31/10/2011
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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

Ciprofloxacin is indicated for treatment of infections caused by susceptible organisms in the conditions listed below: Urinary tract infections; Gonorrhoeal urethritis and cervicitis; Gastroenteritis; Bronchial infections; Skin and skin structure infections; Bone and joint infections; Chronic bacterial prostatitis of mild or moderate severity. Inhalational anthrax (post-exposure): To reduce the incidence or progression of disease following exposure to aerosolised Bacillus anthracis. Ciprofloxacin serum concentrations achieved in humans serve as a surrogate endpoint reasonably likely to predict clinical benefit and provide the basis for this indication. Note: 1. Typhoid and paratyphoid infections and infections due to multi-resistant Staphylococcus aureus are excluded from the above due to insufficient data. 2. Because gram-positive organisms are generally less sensitive to ciprofloxacin, it may not be the drug of choice in cases with Gram-positive infections, such as pneumonia due to Streptococcus pneumoniae. 3. Chronic bacterial prostatitis should be demonstrated by microbiological evidence localising infection to the prostate. Strains of Neisseria gonorrhoea resistant to ciprofloxacin have been reported in Australia. Appropriate culture and susceptibility tests should be performed before treatment in order to determine organism susceptibility to ciprofloxacin and after treatment as warranted by the clinical condition. Therapy with ciprofloxacin may be initiated before results of these tests are known; once results become available, appropriate therapy should be continued. Ciprofloxacin is suitable to treat mixed infections caused by susceptible strains of both Gram-negative and Gram-positive aerobic bacteria. If anaerobic organisms are suspected as accompanying aetiological agents, additional therapy should be considered.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/Al	3 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
20 tablets	(S4) Prescription Only Medicine
10 tablets	(S4) Prescription Only Medicine
14 tablets	(S4) Prescription Only Medicine
8 tablets	(S4) Prescription Only Medicine
100 tablets	(S4) Prescription Only Medicine

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Components

1 . Medicine Component

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	White to creamish white, capsule-shaped, film-coated tablets with "CPR 500" embossed and a break line on one side and "BL" embossed on the other side.

Active Ingredients

ciprofloxacin	500 mg
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Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
macrogol 4000
magnesium stearate
maize starch
microcrystalline cellulose
purified talc
sodium starch glycollate
titanium dioxide

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