



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	114045	CIROFAXIN ciprofloxacin 750mg (as hydrochloride monohydrate) tablet blister pack
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Strides Pharma Science Pty Ltd	
<b>Postal Address</b>	5/148-152 Spit Road, Mosman, NSW, 2088 Australia	
<b>ARTG Start Date</b>	5/11/2004	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 750mg (as hydrochloride monohydrate) tablet blister pack**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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
100 tablets	(S4) Prescription Only Medicine
20 tablets	(S4) Prescription Only Medicine
14 tablets	(S4) Prescription Only Medicine
10 tablets	(S4) Prescription Only Medicine
8 tablets	(S4) Prescription Only Medicine

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**Components**

**1 . Medicine Component**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	White to creamish white, capsule-shaped, film-coated tablets with "CPR 750" embossed on one side and "BL" embossed on the other side.

**Active Ingredients**

ciprofloxacin	<b>750 mg</b>
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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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