



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	166834	Ciprofloxacin 500mg film-coated Tablets bulk
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Arrow Pharma Pty Ltd	
Postal Address	15 - 17 Chapel Street, Cremorne, VIC, 3121 Australia	
ARTG Start Date	16/11/2009	
Product Category	Medicine	
Status	Active	
Approval Area	Export only Medicines	

Conditions

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

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, other than condition No. 8 and condition No. 9.

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, other than condition No.11

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1 . Ciprofloxacin 500mg film-coated Tablets bulk

Product Type	Single Medicine Product	Effective Date	16/11/2009
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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

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bulk Container	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 .

Dosage Form Tablet, film coated

Route of Administration



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Oral

Visual Identification White round convex, scored film-coated tablets with "CR" and "250" interspersed with a break line embossed on one

Active Ingredients

ciprofloxacin hydrochloride **582.21 mg**

Other Ingredients (Excipients)

colloidal anhydrous silica

crospovidone

macrogol 3000

magnesium stearate

maize starch

microcrystalline cellulose

polyvinyl alcohol

pregelatinised maize starch

purified talc

titanium dioxide

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