Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	289487 DULOXETINE AP duloxetine (as hydrochloride) 60 mg enteric capsule bottle
ARTG entry for	Medicine Registered
Sponsor	Arrow Pharma Pty Ltd
Postal Address	15 - 17 Chapel Street, Cremorne, VIC, 3121 Australia
ARTG Start Date	31/07/2018
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Except where the sponsor has been contracted by an overseas partry 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

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.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

Products

1 . DULOXETINE AP duloxetine (as hydrochloride) 60 mg enteric capsule bottle

Product Type	Single Medicine Product	**Effective Date**	14/05/2021

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

DULOXETINE AP is indicated for the treatment of:
· major depressive disorder (MDD)
· diabetic peripheral neuropathic pain (DPNP)
· generalised anxiety disorder (GAD)

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	HDPE	24 Months	Store below 25	Neither child resistant	Not recorded

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	degrees Celsius	closure nor restricted flow insert

Pack Size/Poison information

Pack Size	Poison Schedule
500	(S4) Prescription Only Medicine

Components

1 . DULOXETINE AP duloxetine (as hydrochloride) 60 mg enteric capsule bottle

Dosage Form	Capsule, enteric
Route of Administration	Oral
Visual Identification	Size 1 Blue/green opaque hard gelatin capsules imprinted with 'E' and '129' in black ink containing off-white to beige/salmon spherical pellets.

Active Ingredients

duloxetine hydrochloride	**67.356 mg**

Other Ingredients (Excipients)

butan-1-ol
ethanol
Gelatin
hypromellose
indigo carmine
iron oxide black
iron oxide yellow
isopropyl alcohol
maize starch
methacrylic acid - ethyl acrylate copolymer (1:1)
potassium hydroxide
propylene glycol
purified talc
purified water
Shellac
strong ammonia solution
sucrose
titanium dioxide
triethyl citrate