Public Summary

Summary for ARTG Entry:	409178 FELODIPINE AZN ER felodipine 10 mg extended release tablet blister pack
ARTG entry for	Medicine Registered
Sponsor	AstraZeneca Pty Ltd
Postal Address	PO Box 131, NORTH RYDE, NSW, 1670 Australia
ARTG Start Date	27/07/2023
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"

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 February 1992, 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 February 1992, other than condition No. 11.

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 . FELODIPINE AZN ER felodipine 10 mg extended release tablet blister pack

Product Type	Single Medicine Product	**Effective Date**	27/07/2023

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

Hypertension.

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/PVDC/Al	36 Months	Store below 25 degrees Celsius	Child resistant closure	Protect from Moisture

Pack Size/Poison information

Pack Size	Poison Schedule
30	(S4) Prescription Only Medicine

Components

1 . FELODIPINE AZN ER felodipine 10 mg extended release tablet blister pack

Dosage Form	Tablet, modified release
Route of Administration	Oral
Visual Identification	Circular, red-brown, biconvex film-coated tablet with A/FE impressed on one side and 10 on the other side; 9 mm diameter

Active Ingredients

felodipine	**10 mg**

Other Ingredients (Excipients)

aluminium sodium silicate
Carnauba Wax
hyprolose
hypromellose
iron oxide red
iron oxide yellow
lactose
macrogol 6000
microcrystalline cellulose
PEG-40 hydrogenated castor oil
propyl gallate
sodium stearylfumarate
titanium dioxide