Public Summary

Summary for ARTG Entry:	12309	LONITEN minoxidil 10mg tablet bottle

ARTG entry for	Medicine Registered
Sponsor	Pfizer Australia Pty Ltd
Postal Address	Level 17 151 Clarence Street, Sydney, NSW, 2000 Australia
ARTG Start Date	2/08/1991
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 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 . LONITEN minoxidil 10mg tablet bottle

Product Type	Single Medicine Product	**Effective Date**	8/04/2020

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

INDICATIONS AS AT 1 JANUARY 1991 : Indicated as adjunctive therapy in adults with severe refractory hypertension which has failed to respond to extensive multiple therapy. When used in combination with an accompanying diuretic and beta-blocker, minoxidil (LONITEN) has been shown to reverse encephalopathy and retinopathy in severe hypertensives.

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	3 Years	Store below 25 degrees Celsius	Child resistant closure	Protect from Moisture

Pack Size/Poison information

Pack Size	Poison Schedule
100	(S4) Prescription Only Medicine

Components

1 . Medicine Component

Dosage Form	Tablet, uncoated
Route of Administration	Oral
Visual Identification	White, circular, half oval, scored tablet marked "10" on the obverse side and "U/137" on the reverse side.

Active Ingredients

minoxidil	**10 mg**

Other Ingredients (Excipients)

colloidal anhydrous silica

lactose monohydrate

magnesium stearate

maize starch

microcrystalline cellulose

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