




**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	380813	ONPATTRO patisiran 10 mg/5 mL concentrated injection for infusion vial
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Anylam Australia Pty Ltd	
<b>Postal Address</b>	12 Malcom Street, Narrabeen, NSW, 2101 Australia	
<b>ARTG Start Date</b>	21/11/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Drug Safety Evaluation Branch	

  
**Medicine under  
additional monitoring**

### 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 . ONPATTRO patisiran 10 mg/5 mL concentrated injection for infusion vial

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/09/2023 9:56:08 AM
---------------------	-------------------------	-----------------------	----------------------

#### 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

Onpattro is indicated for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy.

#### Warnings

See Product Information and Consumer Medicine Information for this product

#### Additional Product information

*This product is included in the Black Triangle Scheme*

#### Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	36 Months	Store at 2 to 8 degrees Celsius	Not recorded	Refrigerate Do not Freeze

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
Single vial	(S4) Prescription Only Medicine

#### Components

##### 1 . ONPATTRO patisiran 10 mg/5 mL concentrated injection for infusion vial

<b>Dosage Form</b>	Injection, concentrated
<b>Route of Administration</b>	Intravenous Infusion
<b>Visual Identification</b>	A sterile, preservative-free, white to off-white, opalescent, homogeneous liquid for intravenous infusion in a Type I clear glass vial.

#### Active Ingredients

Public Summary



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

patisiran

10 mg

**Other Ingredients (Excipients)**

cholesterol

dibasic sodium phosphate heptahydrate

distearoylphosphatidylcholine

DLin-MC3-DMA

monobasic potassium phosphate

PEG2000-C-DMG

sodium chloride

water for injections

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary