



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

## Public Summary

<b>Summary for ARTG Entry:</b>	196945	ARZERRA ofatumumab (rnc) 100mg/5mL injection concentrate vial
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Novartis Pharmaceuticals Australia Pty Ltd	
<b>Postal Address</b>	PO Box 101, NORTH RYDE, NSW, 1670 Australia	
<b>ARTG Start Date</b>	11/02/2013	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Drug Safety Evaluation Branch	

**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 . ARZERRA ofatumumab (rnc) 100mg/5mL injection concentrate vial

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	15/06/2018
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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**

1. Previously Untreated CLL:  
ARZERRA is indicated, in combination with chlorambucil or bendamustine, for the treatment of patients with chronic lymphocytic leukaemia (CLL) who have not received prior therapy and are inappropriate for fludarabine-based therapy..2. Refractory CLL:  
ARZERRA, as a single agent, is indicated for the treatment of patients chronic lymphocytic leukaemia (CLL) refractory to fludarabine and alemtuzumab.

**Warnings**  
See Product Information and Consumer Medicine Information for this product

**Additional Product information**

#### Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	3 Years	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Do not Freeze Protect from Light

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
3 vials	(S4) Prescription Only Medicine

#### Components

##### 1 . ARZERRA ofatumumab (rnc)100mg/5mL injection concentrate vial

<b>Dosage Form</b>	Injection, concentrated
<b>Route of Administration</b>	Intravenous Infusion
<b>Visual Identification</b>	A clear to hazy, colourless to pale yellow liquid, practically free of visible particles.

**Active Ingredients**

Ofatumumab	20 mg/mL
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**Other Ingredients (Excipients)**

arginine

disodium edetate

hydrochloric acid

polysorbate 80

sodium acetate

sodium chloride

water for injections

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