



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	349072	COVID-19 Vaccine AstraZeneca (ChAdOx1-S) solution for injection multidose vial
<b>ARTG entry for</b>	Medicine Registered (Provisional)	
<b>Sponsor</b>	AstraZeneca Pty Ltd	
<b>Postal Address</b>	PO Box 131, NORTH RYDE, NSW, 1670 Australia	
<b>ARTG Start Date</b>	16/02/2021	
<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 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 party 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 . COVID-19 Vaccine AstraZeneca (ChAdOx1-S) solution for injection multidose vial**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	17/05/2021
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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**

**Provisionally Registered Indications**

COVID-19 Vaccine AstraZeneca has provisional approval for the indication:  
Active immunisation of individuals 18 years old for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.  
The use of this vaccine should be in accordance with official recommendations.  
The decision has been made on the basis of short term efficacy and safety data. Continued approval is dependent upon the evidence of longer-term efficacy and safety from ongoing clinical trials and post-market assessment.

**Provisionally Registered Conditions**

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**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	6 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Store in Original Container Protect from Light Do not Shake Do not Freeze

**Pack Size/Poison information**

Pack Size	Poison Schedule
5mL (10 x 0.5mL dose) in 6mL, 10mL or 10R vial - 10 vials per pack	(S4) Prescription Only Medicine
4mL (8 x 0.5mL dose) in 5mL vial - 10 vials per pack	(S4) Prescription Only Medicine

**Components**

**1 . COVID-19 Vaccine AstraZeneca (ChAdOx1-S) solution for injection multidose vial**

<b>Dosage Form</b>	Injection, solution
<b>Route of Administration</b>	Intramuscular
<b>Visual Identification</b>	Clear to slightly opaque, colourless to slightly brown, particle free solution in clear glass vial, elastomeric stopper & aluminium overseal

**Active Ingredients**

<b>ChAdOx1-S</b>	<b>100000000000 vp/mL</b>
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**Other Ingredients (Excipients)**

disodium edetate  
ethanol absolute  
histidine hydrochloride monohydrate  
histidine  
magnesium chloride hexahydrate  
polysorbate 80  
sodium chloride  
sucrose  
water for injections

Public Summary

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