



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	350150	COVID-19 VACCINE JANSSEN Ad26.COVS.2.S 5x10 ¹⁰ VP/0.5mL suspension for injection vial
ARTG entry for	Medicine Registered (Provisional)	
Sponsor	Janssen-Cilag Pty Ltd	
Postal Address	Locked Bag 2070, NORTH RYDE, NSW, 1670 Australia	
ARTG Start Date	25/06/2021	
Product Category	Medicine	
Status	Active	
Approval Area	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 . COVID-19 VACCINE JANSSEN Ad26.COVS.2.S 5x10¹⁰ VP/0.5mL suspension for injection vial

Product Type	Single Medicine Product	Effective Date	25/06/2021
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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 Janssen has provisional approval for the indication;. COVID-19 Vaccine Janssen is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. 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

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	3 Months	Store at 2 to 8 degrees Celsius	Not recorded	Protect from Light Store in Original Container

Pack Size/Poison information

Pack Size	Poison Schedule
10	(S4) Prescription Only Medicine

Components

1 . COVID-19 VACCINE JANSSEN Ad26.COVS.2.S 5x10¹⁰ VP/0.5mL suspension for injection vial

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Dosage Form Injection, suspension
Route of Administration Intramuscular
Visual Identification Colourless to slightly yellow, clear to very opalescent suspension

Active Ingredients

Ad26.COV2.S 50000000000 vp

Other Ingredients (Excipients)

citric acid monohydrate
ethanol absolute
hydrochloric acid
hydroxypropylbetadex
polysorbate 80
sodium chloride
sodium citrate dihydrate
sodium hydroxide
water for injections

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