



Public Assessment Report

National Procedure

COVID-19 Vaccine Janssen suspension for injection

PLGB 00242/0742

COVID-19 vaccine (Ad26.COV2-S [recombinant])

The Public Assessment Report summarises the initial assessment at the time of approval in May 2021. The text in the original report remains unchanged.

Our advice is regularly updated on the basis of significant new data and our latest advice can be found in the [Summary of Product Characteristics](#).

Janssen-Cilag Ltd

LAY SUMMARY

COVID-19 Vaccine Janssen suspension for injection (COVID-19 vaccine (Ad26.COV2-S [recombinant]))

This is a summary of the Public Assessment Report (PAR) for COVID-19 Vaccine Janssen suspension for injection. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product was approved with a national conditional Marketing Authorisation (CMA) which is used for medicinal products that fulfill an unmet medical need.

This product will be referred to as COVID-19 Vaccine Janssen in this lay summary for ease of reading.

For practical information about using COVID-19 Vaccine Janssen, patients should read the [Patient Information Leaflet \(PIL\)](#) or contact their doctor or pharmacist.

What is COVID-19 Vaccine Janssen and what is it used for?

COVID-19 Vaccine Janssen is a vaccine indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

This product has been authorised by MHRA in Great Britain (consisting of England, Scotland and Wales). This procedure follows a European Commission (EC) decision on 11 March 2021 (EMA/H/C/005737), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP). This is known as the EC Decision Reliance Procedure.

How does COVID-19 Vaccine Janssen work?

COVID-19 Vaccine Janssen causes the body's natural defenses (immune system) to produce antibodies and specialized white blood cells that work against the virus, so giving protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

How is COVID-19 Vaccine Janssen used?

The pharmaceutical form of this medicine is a suspension for injection and the route of administration is intramuscular injection. COVID-19 Vaccine Janssen is for intramuscular injection only, preferably in the deltoid muscle of the upper arm.

You will receive 1 injection of COVID-19 Vaccine Janssen of 0.5 mL.

For further information on how COVID-19 Vaccine Janssen is used, refer to the [PIL](#) and [Summary of Product Characteristics \(SmPC\)](#) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This vaccine can only be obtained with a prescription.

The patient should ask the administering healthcare practitioner if they have any questions concerning the vaccine.

What are the possible side effects of COVID-19 Vaccine Janssen?

For the full list of all side effects reported with this medicine, see Section 4 of the [PIL](#) or the [SmPC](#) available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on behalf of someone else they care for, directly via the Yellow Card scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

The most common side effects with COVID-19 Vaccine Janssen (which may affect more than 1 in 10 people) are headache, nausea, muscle aches, pain where the injection is given and feeling very tired.

Why was COVID-19 Vaccine Janssen approved?

MHRA decided that the benefits are greater than the risks and recommended that this medicine can be approved for use.

COVID-19 Vaccine Janssen has been authorised with a Conditional Marketing Authorisation (CMA). CMAs are intended for medicinal products that fulfil an unmet medical need, such as for serious and life-threatening diseases where no satisfactory treatment methods are available or where the product offers a major therapeutic advantage. CMAs may be granted where comprehensive clinical data is not yet complete, but it is judged that such data will become available soon. Adequate evidence of safety and efficacy to enable the MHRA to conclude that the benefits are greater than the risks is required. Any new information on COVID-19 Vaccine Janssen will be reviewed every year and this report will be updated as necessary.

What measures are being taken to ensure the safe and effective use of COVID-19 Vaccine Janssen?

A Risk Management Plan (RMP) has been developed to ensure that COVID-19 Vaccine Janssen is used as safely as possible. Based on this plan, safety information has been included in the [SmPC](#) and the [PIL](#), including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

Other information about COVID-19 Vaccine Janssen

A marketing authorisation was granted in Great Britain (consisting of England, Scotland and Wales) on 28 May 2021.

The full PAR for COVID-19 Vaccine Janssen follows this summary.

This summary was last updated in June 2021.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for COVID-19 Vaccine Janssen suspension for injection (PLGB 00242/0742) could be approved.

The product is approved for the following indications:

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 name of the active substance is COVID-19 vaccine (Ad26.COV2-S [recombinant]). COVID-19 Vaccine Janssen is a monovalent vaccine composed of a recombinant, replication-incompetent human adenovirus type 26 vector that encodes a SARS-CoV-2 full-length spike (S) glycoprotein in a stabilised conformation. Following administration, the S glycoprotein of SARS-CoV-2 is transiently expressed, stimulating both neutralising and other functional S-specific antibodies, as well as cellular immune responses directed against the S antigen, which may contribute to protection against COVID-19.

This product has been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). This procedure relies on a European Commission (EC) decision on 11 March 2021 (EMA/H/C/005737), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP). For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the European Medicines Agency (EMA), please refer to the European Public Assessment Report, available on the EMA website.

This application was submitted under Regulation 50 of the Human Medicines Regulation 2012, as amended (previously Article 8(3) of Directive 2001/83/EC, as amended).

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Advice was sought from the Commission of Human Medicines (CHM) on 6 May 2021 as Covid-19 products, are of major Public Health interest.

A Conditional Marketing Authorisation was granted on 28 May 2021.

II. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with current guidelines and is/are satisfactory.

PATIENT INFORMATION LEAFLET

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for this application is satisfactory.

The grant of a marketing authorisation is recommended.

IV. NON-CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation is recommended.

V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation is recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. In addition to routine pharmacovigilance and risk minimisation measures, the following additional risks and safety measures have been proposed:

Additional pharmacovigilance activities have been proposed comprising of 11 studies to further evaluate safety and effectiveness, and to supply further information in the post marketing setting. The studies include six interventional studies and five non-interventional studies (five safety and two on effectiveness).

Study Status	Summary of Objectives	Safety Concerns Addressed	Milestones	Due Dates
Category 2 – Imposed mandatory additional pharmacovigilance activities which are Specific Obligations in the context of a conditional marketing authorisation or a marketing authorisation under exceptional circumstances				
A randomized, double-blind, placebo-controlled Phase 3 study to assess the efficacy and safety of Ad26.COVS.2 for the prevention of SARS-CoV-2-mediated COVID-19 in adults aged 18 years and older (VAC31518COV3001) Ongoing	To evaluate the efficacy, safety, reactogenicity, and immunogenicity of Ad26.COVS.2 for the prevention of SARS-CoV-2-mediated COVID-19.	Anaphylaxis Vaccine-associated enhanced disease (VAED), including vaccine-associated enhanced respiratory disease (VAERD) Venous thromboembolism Use in pregnancy and while breastfeeding (This trial will only address use while breastfeeding) Use in frail patients with comorbidities (e.g., chronic obstructive pulmonary disease [COPD], diabetes, chronic neurological disease, cardiovascular disorders) Long-term safety	Final study report	31 December 2023
Category 3 – Required additional pharmacovigilance activities				
A randomized, double-blind, placebo-controlled	To evaluate the efficacy, safety,	Anaphylaxis Vaccine-associated	Final study report	30 June 2024

Study Status	Summary of Objectives	Safety Concerns Addressed	Milestones	Due Dates
Phase 3 study to assess the efficacy and safety of Ad26.COV2.S for the prevention of SARS-CoV-2-mediated COVID-19 in adults aged 18 years and older (VAC31518COV3009) Ongoing	reactogenicity, and immunogenicity of 2 doses of Ad26.COV2.S for the prevention of SARS-CoV-2-mediated COVID-19.	enhanced disease (VAED), including vaccine-associated enhanced respiratory disease (VAERD) Venous thromboembolism Use in pregnancy and while breastfeeding (This trial will only address use while breastfeeding) Long-term safety		
An open-label, Phase 2 study to evaluate the safety, reactogenicity, and immunogenicity of Ad26.COV2.S in healthy pregnant participants (VAC31518COV2004) Planned	To assess the safety, reactogenicity, and immunogenicity of Ad26.COV2.S in adult participants during the 2 nd and/or 3 rd trimester of pregnancy, to assess the safety and reactogenicity of Ad26.COV2.S (potentially) post-partum, and to assess pregnancy outcomes. To assess the presence of immunoglobulins against SARS-CoV-2 in colostrum and breast milk.	Use in pregnancy and while breastfeeding	Protocol submission Final study report	06 March 2021 30 September 2023
Interventional trial to evaluate the safety and immunogenicity of Ad26.COV2.S in immunocompromised patients Planned	To assess the safety and immunogenicity of Ad26.COV2.S in immunocompromised patients.	Use in immunocompromised patients	Final study report	30 June 2023
COVID-19 Vaccines International Pregnancy Exposure Registry (C-VIPER) (VAC31518COV4005) Planned	To assess the occurrence of obstetric, neonatal, and infant outcomes among women administered with Ad26.COV2.S during pregnancy.	Use in pregnancy and while breastfeeding (<i>This study will only address use in pregnancy</i>)	Protocol submission Final study report	15 February 2021 30 June 2027
Post-authorisation, observational study to assess the safety of Ad26.COV2.S using electronic health record (EHR) database(s) in Europe (VAC31518COV4003) Planned	To assess the occurrence of pre-specified AESIs within specific risk periods following administration of Ad26.COV2.S.	Anaphylaxis Venous thromboembolism Use in immunocompromised patients Use in patients with autoimmune or inflammatory disorders Use in frail patients with comorbidities (e.g., chronic obstructive pulmonary disease [COPD],	Protocol submission Final study report	15 May 2021 30 June 2024

Study Status	Summary of Objectives	Safety Concerns Addressed	Milestones	Due Dates
		diabetes, chronic neurological disease, cardiovascular disorders) Long-term safety Use in pregnancy and while breastfeeding <i>(The adequacy of the study to address pregnancy outcomes is to be assessed. The safety of Ad26.COV2.S in breastfeeding women will not be studied.)</i>		
Post-authorisation, observational, prospective study to assess the effectiveness of Ad26.COV2.S in Europe (VAC31518COV4004) Planned	To estimate the effectiveness of Ad26.COV2.S in preventing laboratory-confirmed SARS-CoV-2 hospitalizations up to 2 years post-vaccination.	Vaccine-associated enhanced disease (VAED), including vaccine-associated enhanced respiratory disease (VAERD) Use in immunocompromised patients	Protocol submission Final study report	31 March 2021 30 June 2024
Post-authorisation, observational study to assess the safety of Ad26.COV2.S using health insurance claims and/or electronic health record (EHR) database(s) in the United States (VAC31518COV4001) Planned	To assess the occurrence of pre-specified AESIs within specific risk periods following administration of Ad26.COV2.S.	Anaphylaxis Venous thromboembolism Use in immunocompromised patients Use in patients with autoimmune or inflammatory disorders Use in frail patients with comorbidities (e.g., chronic obstructive pulmonary disease [COPD], diabetes, chronic neurological disease, cardiovascular disorders) Long-term safety	Protocol submission Final study report	30 June 2021 31 December 2024
Post-authorisation, observational study to assess the effectiveness of Ad26.COV2.S using health insurance claims and/or electronic health record (EHR) database(s) in the United States (VAC31518COV4002) Planned	To estimate the effectiveness of Ad26.COV2.S in preventing medically-attended COVID-19 up to 2 years post-vaccination.	Vaccine-associated enhanced disease (VAED), including vaccine-associated enhanced respiratory disease (VAERD) Use in immunocompromised patients	Protocol submission Final study report	30 June 2021 31 December 2024
Coadministration study of Ad26.COV2.S with seasonal influenza vaccine	To assess the safety and immunogenicity of Ad26.COV2.S and seasonal influenza vaccine when	Interaction with other vaccines	Interim analysis report Final study	31 December 2022 31 December

Study Status	Summary of Objectives	Safety Concerns Addressed	Milestones	Due Dates
Planned	administered separately or concomitantly.		report	2023
A randomized, double-blind, placebo-controlled Phase 2a study to evaluate a range of dose levels and vaccination intervals of Ad26.COV2.S in healthy adults aged 18 to 55 years inclusive and adults aged 65 years and older and to evaluate 2 dose levels of Ad26.COV2.S in healthy adolescents aged 12 to 17 years inclusive (VAC31518COV2001)	To evaluate the efficacy, safety, reactogenicity, and immunogenicity of Ad26.COV2.S at different dose levels and as a 2-dose or a 1-dose schedule.	Venous thromboembolism	Final study report	31 December 2023
Ongoing				

This is acceptable.

VII. USER CONSULTATION

The PIL has been evaluated via a user consultation study in accordance with legal requirements. The results show that the PIL meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

COVID-19 Vaccine Janssen suspension for injection has been authorised with a Conditional Marketing Authorisation (CMA). The Marketing Authorisation Holder shall complete, within the stated timeframe, the following measures:

Description	Due date
In order to confirm the consistency of the finished product manufacturing process, the applicant should provide additional validation and comparability data.	30 September 2021 Combined interim report: 31 May 2021
In order to confirm the efficacy and safety of Ad26.COV2.S COVID-19 vaccine, the MAH should submit the final Clinical Study Report for the randomised, placebo-controlled, observer-blind study VAC31518COV3001.	31 December 2023
To submit a variation to update the Risk Management Plan in-line with the step 1 revisions requested in the PRAC report EMA/PRAC/227875/2021 (Signal of Embolic and Thrombotic events (SMQ) with COVID-19 Vaccine Janssen (Ad26.COV2-S [recombinant])	Within 14 days of CMA approval
To submit a variation to further update the Risk Management Plan in-line with the step	Within 90 days of CMA approval

Description	Due date
2 revisions requested in the PRAC report EMA/PRAC/227875/2021 (Signal of Embolic and Thrombotic events (SMQ) with COVID-19 Vaccine Janssen (Ad26.COV2-S [recombinant])	

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for the product are available on the MHRA website.

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Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	Scope	Product information affected	Date of grant	Outcome	Assessment report attached Y/N