

Public Assessment Report

National Procedure

COVID-19 Vaccine Moderna, 0.20 mg/mL dispersion for injection

(COVID-19 mRNA Vaccine [nucleoside modified])

PLGB 53720/0002

The Public Assessment Report summarises the initial assessment at the time of approval in January 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](#) and the [Summary of Coronavirus Yellow Card reporting](#).

Moderna Biotech Spain, S.L.

LAY SUMMARY

COVID-19 Vaccine Moderna, 0.20 mg/mL dispersion for injection (COVID-19 mRNA Vaccine [nucleoside modified])

This is a summary of the Public Assessment Report (PAR) for COVID-19 Vaccine Moderna, 0.20 mg/mL dispersion 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 Moderna in this lay summary for ease of reading.

For practical information about using COVID-19 Vaccine Moderna, patients should read the [Package leaflet: Information for the user](#) or contact their doctor or pharmacist.

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

COVID-19 Vaccine Moderna is a vaccine indicated for active immunisation to prevent coronavirus disease 19 (COVID-19) caused by the SARS-CoV-2 virus 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 6 January 2021 (EMA/H/C/005791), 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 Moderna work?

COVID-19 Vaccine Moderna stimulates the body's natural defences (immune system) and causes the body to produce its own protection (antibodies) against the virus. None of the ingredients in this vaccine can cause COVID-19.

How is COVID-19 Vaccine Moderna used?

The pharmaceutical form of this medicine is a dispersion for injection and the route of administration is intramuscular injection. COVID-19 Vaccine Moderna will be given to you by an authorised practitioner as an intramuscular injection into the muscle at the top of the upper arm (deltoid muscle).

You will receive 2 injections of COVID-19 Vaccine Moderna, each of 0.5ml. It is recommended to administer the second dose 28 days after the first.

For further information on how COVID-19 Vaccine Moderna is used, refer to the [Summary of Product Characteristics \(SmPC\)](#) and the [Package leaflet: Information for the user](#) 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 benefits of COVID-19 Vaccine Moderna have been shown in studies?

COVID-19 Vaccine Moderna was given to 15,185 individuals aged 18 years or older in the main clinical study, including 3,768 individuals aged 65 years and older. The study included participants with one or more other medical conditions that increase the risk of severe COVID-19 disease, such as chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease or HIV infection.

In the primary efficacy analysis, there were 11 cases of COVID-19 reported in the vaccine group compared with 185 cases reported in the placebo group. Vaccine efficacy against COVID-19 was 94.1%. These results were observed starting 2 weeks after the second dose in study participants with no evidence of prior SARS-CoV-2 infection.

The level of protection gained after dose 1 was assessed in an exploratory analysis. In the interval 14 days after dose 1 to dose 2, there were 35 cases of COVID-19 on placebo and only 2 in the vaccine group. This indicates a high level of protection from 14 days after the first dose and before receiving dose 2.

The efficacy of COVID-19 Vaccine Moderna was consistent between older subjects (≥ 65 years) and younger subjects (18 - 64 years).

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

The most common side effects with COVID-19 Vaccine Moderna (which may affect more than 1 in 10 people) are injection site pain, feeling tired, headache, muscle ache, joint aches/stiffness, chills, nausea, vomiting, swelling of the underarm glands, fever and injection site swelling.

For the full list of all side effects reported with this medicine, see The [Summary of Product Characteristics \(SmPC\)](#) or [Package leaflet: Information for the user](#) available on the MHRA website.

Why was COVID-19 Vaccine Moderna approved?

It was concluded that COVID-19 Vaccine Moderna has been shown to be effective in the prevention of COVID-19. Furthermore, the side effects observed with use of this product are considered to be similar to those seen for other vaccines. Therefore, the MHRA concluded that this medicine can receive a conditional marketing authorisation.

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

All new medicines approved require a Risk Management Plan (RMP) to ensure they are used as safely as possible. An RMP has been agreed for the use of COVID-19 Vaccine Moderna in the UK. Based on this plan, safety information has been included in the [Summary of Product Characteristics \(SmPC\)](#) and the [Package leaflet: Information for the user](#), including the appropriate precautions to be followed by healthcare professionals and patients.

All side effects reported by patients/healthcare professionals are continuously monitored. Any new safety signals identified will be reviewed and, if necessary, appropriate regulatory action will be taken. The MHRA has also put in place an additional proactive safety monitoring plan for all COVID-19 vaccines to enable rapid analysis of safety information which is important during a pandemic.

Other information about COVID-19 Vaccine Moderna

A conditional marketing authorisation was granted in Great Britain (consisting of England, Scotland and Wales) on 31 March 2021.

The public assessment report for COVID-19 Vaccine Moderna follows this summary.

This summary was last updated 7 April 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 Moderna dispersion for injection (PLGB 53720/0002) could be approved.

The name of the active substance is COVID-19 mRNA Vaccine (nucleoside modified). COVID-19 Vaccine Moderna is a dispersion for injection intended for intramuscular administration (IM). COVID-19 Vaccine Moderna multiple-dose vials are stored at -25°C to -15°C until ready for use. Vials are packed in cartons containing ten multiple-dose vials per carton. The vials are type 1 glass (or equivalent), sealed with a chlorobutyl rubber stopper and an aluminium seal.

Each vial contains 10 doses (each 0.5 mL) and one dose contains 0.10mg mRNA (embedded in lipid nanoparticles). COVID-19 mRNA Vaccine is single-stranded, 5'-capped messenger RNA (mRNA) produced using cell-free *in vitro* transcription, encoding the pre-fusion stabilized spike (S) glycoprotein of SARS-CoV-2.

In addition to COVID-19 mRNA Vaccine, this product also contains the excipients lipid SM-102, cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG), trometamol (Tris), trometamol hydrochloride (Tris-HCl), acetic acid, sodium acetate trihydrate, sucrose and water for injection.

No materials of human or animal origin were used in the manufacture of COVID-19 Vaccine Moderna.

The product is approved for the following indications:

COVID-19 Vaccine Moderna 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 SARS-CoV-2 virus uses proteins on its outer surface, called spike (S) proteins, to enter the cells of the body and cause disease. COVID-19 Vaccine Moderna contains the genetic code for the spike protein of SARS-CoV-2. Following vaccine administration, the lipid nanoparticle delivers the mRNA to cells of the body. The mRNA encodes for the spike protein mRNA sequence and is translated within the cells and produces the spike protein of SARS-CoV-2. The spike protein is then expressed on the surface of the cells which induces neutralising antibodies and T-cells to be raised against it. Should the body then become infected with SARS-CoV-2, the immune system will recognise the SARS-CoV-2 virus and attack it.

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 6 January 2021 (EMA/H/C/005791), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP).

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, analysis, 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.

A Conditional Marketing Authorisation was granted on 31 March 2021.

II. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION

Summary of Product Characteristics (SmPC)

The SmPC is in line with current guidelines and is 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, NON-CLINICAL AND CLINICAL ASPECTS

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

The full data are available at https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf

The grant of a conditional marketing authorisation is recommended.

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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

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