EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

← Medicines

Vaxzevria (previously COVID-19 Vaccine AstraZeneca)

COVID-19 Vaccine (ChAdOx1-S [recombinant])

Medicine Human

Withdrawn

This medicine's authorisation has been withdrawn

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- **European Commission decision**

Overview

The marketing authorisation for Vaxzevria (SRD) has been withdrawn at the request of the marketing-authorisation holder.

Vaxzevria (previously COVID-19 Vaccine AstraZeneca) : EPAR - Medicine overview

Reference Number: EMA/609262/2021

English (EN) (314.66 KB - PDF)

First published: 18/02/2021

Last updated: 07/05/2024

View

Other languages (22)

Vaxzevria (previously COVID-19 Vaccine AstraZeneca) : EPAR - Risk-management-plan

English (EN) (3.02 MB - PDF)

First published: 18/02/2021

Last updated: 07/05/2024

View

Product information

Vaxzevria : EPAR - Product information

English (EN) (709.52 KB - PDF)

First published: 18/02/2021

Last updated: 07/05/2024

View

Other languages (24)

Latest procedure affecting product information:
II/0096

07/03/2024

This medicine's product information is available in all **official EU languages**.
Select 'available languages' to access the language you need.

Product information documents contain:

- summary of product characteristics (annex I);
- manufacturing authorisation holder responsible for batch release (annex IIA);
- conditions of the marketing authorisation (annex IIB);
- labelling (annex IIIA);
- package leaflet (annex IIIB).

Vaxzevria (previously COVID-19 Vaccine AstraZeneca) : EPAR - All authorised presentation

English (EN) (57.61 KB - PDF)

First published: 18/02/2021

Last updated: 07/05/2024

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Other languages (24)

Product details

BioNTech-Pfizer Exhibit 1283
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358

Name of medicine

Vaxzevria (previously COVID-19 Vaccine AstraZeneca)

Active substance

ChAdOx1-SARS-COV-2

International non-proprietary name (INN) or common name

COVID-19 Vaccine (ChAdOx1-S [recombinant])

Therapeutic area (MeSH)

COVID-19 virus infection

Anatomical therapeutic chemical (ATC) code

J07BN02

Pharmacotherapeutic group

Vaccines

Therapeutic indication

Vaxzevria 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.

Authorisation details

EMA product number

EMEA/H/C/005675

Marketing authorisation holder

AstraZeneca AB

BioNTech-Pfizer Exhibit 1283
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358

151 85 Sodertalje
Sweden

Opinion adopted

29/01/2021

Marketing authorisation issued

29/01/2021

Withdrawal of marketing authorisation

27/03/2024

Revision

32

Assessment history

Changes since initial authorisation of medicine

Initial marketing authorisation documents

Safety updates

Vaxzevria: Periodic safety update report assessment 29 December 2022 to 28 December 2023

English (EN) (15.79 MB - PDF)

First published: 22/08/2024

BioNTech-Pfizer Exhibit 1283
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358

View

COVID-19 vaccines - Safety update: 14 July 2022

Adopted

Reference Number: Rev. 1

English (EN) (263.34 KB - PDF)

First published: 14/07/2022

Last updated: 09/08/2024

View

COVID-19 vaccines - Safety update: 8 September 2022

Adopted

English (EN) (257.73 KB - PDF)

First published: 08/09/2022

Last updated: 09/08/2024

View

COVID-19 vaccines - Safety update: 17 March 2022

Adopted

English (EN) (237.65 KB - PDF)

First published: 17/03/2022

Last updated: 09/08/2024

View

COVID-19 vaccines - Safety update: 6 October 2022

Adopted

English (EN) (237.46 KB - PDF)

First published: 06/10/2022

Last updated: 09/08/2024

View

COVID-19 vaccines - Safety update: 8 December 2022

Reference Number: Rev. 2

English (EN) (239.73 KB - PDF)

First published: 08/12/2022

Last updated: 09/08/2024

View

COVID-19 vaccines - Safety update: 10 November 2022

Adopted

English (EN) (254.94 KB - PDF)

First published: 10/11/2022

Last updated: 09/08/2024

View

COVID-19 vaccines - Safety update: 12 May 2022

Adopted

BioNTech-Pfizer Exhibit 1283
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358

English (EN) (214.22 KB - PDF)

First published: 12/05/2022

Last updated: 09/08/2024

View

COVID-19 vaccines - Safety update: 13 April 2022

Adopted

English (EN) (228.5 KB - PDF)

First published: 13/04/2022

Last updated: 09/08/2024

View

COVID-19 vaccines - Safety update: 17 February 2022

Adopted

English (EN) (226.15 KB - PDF)

First published: 17/02/2022

Last updated: 09/08/2024

View

COVID-19 vaccines - Safety update: 17 June 2022

Adopted

English (EN) (249.16 KB - PDF)

First published: 17/06/2022

Last updated: 09/08/2024

View

COVID-19 vaccines - Safety update: 20 January 2022

Adopted

English (EN) (251.15 KB - PDF)

First published: 20/01/2022

Last updated: 09/08/2024

View

COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 8 September 2021

Adopted

English (EN) (492.14 KB - PDF)

First published: 08/09/2021

Last updated: 07/05/2024

View

COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 9 December 2021

Adopted

English (EN) (301.05 KB - PDF)

First published: 09/12/2021

Last updated: 07/05/2024

View

COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 11 August 2021

BioNTech-Pfizer Exhibit 1283
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358

Adopted

English (EN) (280.1 KB - PDF)

First published: 11/08/2021

Last updated: 07/05/2024

View

COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 11 November 2021

Adopted

English (EN) (333.55 KB - PDF)

First published: 11/11/2021

Last updated: 07/05/2024

View

COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 14 April 2021

Adopted

English (EN) (340.14 KB - PDF)

First published: 16/04/2021

Last updated: 07/05/2024

View

COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 14 July 2021

Adopted

BioNTech-Pfizer Exhibit 1283
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358

English (EN) (347.15 KB - PDF)

First published: 14/07/2021

Last updated: 07/05/2024

View

COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 18 June 2021

Adopted

English (EN) (489.91 KB - PDF)

First published: 18/06/2021

Last updated: 07/05/2024

View

COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 21 May 2021

Adopted

English (EN) (264.25 KB - PDF)

First published: 21/05/2021

Last updated: 07/05/2024

View

COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 29 March 2021

Adopted

English (EN) (413.69 KB - PDF)

First published: 30/03/2021

Last updated: 07/05/2024

View

Vaxzevria: Periodic safety update report assessment 29 December 2021 to 28 June 2022

English (EN) (39.56 MB - PDF)

First published: 18/12/2023

Last updated: 07/05/2024

View

Vaxzevria: Periodic safety update report assessment 29 June 2022 to 28 December 2022

English (EN) (15.04 MB - PDF)

First published: 21/12/2023

Last updated: 07/05/2024

View

COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 6 October 2021

Adopted

English (EN) (115.75 KB - PDF)

First published: 06/10/2021

View

COVID-19 vaccine safety update for Vaxzevria (previously COVID-19 Vaccine AstraZeneca): 11 May 2021

Adopted

English (EN) (87.31 KB - PDF)

First published: 12/05/2021

View

News on Vaxzevria (previously COVID-19 Vaccine AstraZeneca)

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 10-13 October 2022

14/10/2022

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 16-19 May 2022

20/05/2022

Increase in manufacturing capacity for Vaxzevria (previously COVID-19 Vaccine AstraZeneca)

24/01/2022

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 10 - 13 January 2022

14/01/2022

Increase in manufacturing capacity for COVID-19 vaccine from AstraZeneca

01/12/2021

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 27-30 September 2021

01/10/2021

BioNTech-Pfizer Exhibit 1283
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 5 August 2021

06/08/2021

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 7-10 June 2021

11/06/2021

Vaxzevria: EMA advises against use in people with history of capillary leak syndrome

11/06/2021

COVID-19 vaccines: update on ongoing evaluation of myocarditis and pericarditis

11/06/2021

EMA raises awareness of clinical care recommendations to manage suspected thrombosis with thrombocytopenia syndrome

07/06/2021

Vaxzevria: further advice on blood clots and low blood platelets

21/05/2021

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 17-20 May 2021

21/05/2021

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 3-6 May 2021

07/05/2021

AstraZeneca's COVID-19 vaccine: benefits and risks in context

23/04/2021

AstraZeneca's COVID-19 vaccine: EMA to provide further context on risk of very rare blood clots with low blood platelets

14/04/2021

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 6-9 April 2021

09/04/2021

AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets

07/04/2021

AstraZeneca COVID-19 vaccine: review of very rare cases of unusual blood clots continues

31/03/2021

Increase in vaccine manufacturing capacity and supply for COVID-19 vaccines from AstraZeneca, BioNTech/Pfizer and Moderna

26/03/2021

COVID-19 Vaccine AstraZeneca – Update on ongoing evaluation of blood clot cases

25/03/2021

COVID-19 Vaccine AstraZeneca: benefits still outweigh the risks despite possible link to rare blood clots with low blood platelets

18/03/2021

Investigation of COVID-19 Vaccine AstraZeneca and thromboembolic events continues

16/03/2021

EMA's safety committee continues investigation of COVID-19 Vaccine AstraZeneca and thromboembolic events – further

BioNTech-Pfizer Exhibit 1283
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358

update

15/03/2021

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 March 2021

12/03/2021

COVID-19 Vaccine AstraZeneca: PRAC investigating cases of thromboembolic events - vaccine's benefits currently still outweigh risks - Update

11/03/2021

COVID-19 Vaccine AstraZeneca: PRAC preliminary view suggests no specific issue with batch used in Austria

10/03/2021

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 25-29 January 2021

29/01/2021

EMA recommends COVID-19 Vaccine AstraZeneca for authorisation in the EU

29/01/2021

EMA receives application for conditional marketing authorisation of COVID-19 Vaccine AstraZeneca

12/01/2021

Update on rolling review of AstraZeneca's COVID-19 vaccine

30/12/2020

EMA starts first rolling review of a COVID-19 vaccine in the EU

01/10/2020

Signal assessment reports

BioNTech-Pfizer Exhibit 1283
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Signal assessment report on embolic and thrombotic events (SMQ) with COVID-19 Vaccine (ChAdOx1-S [recombinant]) – Vaxzevria (previously COVID-19 Vaccine AstraZeneca) (Other viral vaccines)

Adopted

Reference Number: EMA/205598/2021

English (EN) (3.5 MB - PDF)

First published: 13/04/2021

Last updated: 07/05/2024

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Signal assessment report on embolic and thrombotic events (SMQ) with COVID-19 Vaccine (ChAdOx1-S [recombinant]) – COVID-19 Vaccine AstraZeneca (Other viral vaccines)

Adopted

Reference Number: EMA/PRAC/157045/2021

English (EN) (1.87 MB - PDF)

First published: 31/03/2021

Last updated: 07/05/2024

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Related information on Vaxzevria

- Article-5(3)-opinion: Use of Vaxzevria to prevent COVID-19

External links

- Clinical data (login required)

More information on Vaxzevria (previously COVID-19 Vaccine AstraZeneca)

Public statement on Vaxzevria (previously COVID-19 Vaccine AstraZeneca): Withdrawal of the marketing authorisation in the European Union

Reference Number: EMEA/H/C/005675

English (EN) (117.11 KB - PDF)

First published: 07/05/2024

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More information on Vaxzevria (previously COVID-19 Vaccine AstraZeneca)

- EMEA-002862-PIP01-20-M02 - paediatric investigation plan
- Vaxzevria (previously COVID-19 Vaccine AstraZeneca) - direct healthcare professional communication (DHPC)
- Vaxzevria (previously COVID-19 Vaccine AstraZeneca) - direct healthcare professional communication (DHPC)
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