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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✕ **Withdrawn**

This medicine's authorisation has been withdrawn

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The marketing authorisation for Vaxzevria (SRD) has been withdrawn at the request of the marketing-authorisation holder.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

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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

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Product information



Vaxzevria : EPAR - Product information

English (EN) (709.52 KB - PDF)

First published: 18/02/2021

Last updated: 07/05/2024

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[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[View](#) [Other languages \(24\) ▼](#)**Product details**

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**

EMA/H/C/005675

Marketing authorisation holder

AstraZeneca AB

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

[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

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**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

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

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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

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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. IPR2023-01359

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

English (EN) (347.15 KB - PDF)

First published: 14/07/2021

Last updated: 07/05/2024

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**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

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**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

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**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

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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

[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](#)

[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



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)

- [EMA-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 \(DHPC\)](#)
- [Vaxzevria \(previously COVID-19 Vaccine AstraZeneca\) - direct healthcare professional communication \(DHPC\)](#)
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