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VidPrevtyl Beta

COVID-19 Vaccine (recombinant, adjuvanted)

Medicine

Human



Withdrawn

This medicine's authorisation has been withdrawn



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Rolling review



Application under evaluation



CHMP opinion



European Commission decision

Overview

The marketing authorisation for Vidprevtyl Beta has been withdrawn at the request of the marketing-authorisation holder.



VidPrevtyl Beta : EPAR - Medicine overview

Reference Number: EMA/872778/2022

English (EN) (236.94 KB - PDF)

First published: 11/11/2022

Last updated: 20/03/2024

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VidPrevtyl Beta : EPAR - Risk-management-plan

English (EN) (8.41 MB - PDF)

First published: 11/11/2022

Last updated: 20/03/2024

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Product information



VidPrevtyl Beta : EPAR - Product information

English (EN) (1.33 MB - PDF)

First published: 10/11/2022

Last updated: 20/03/2024

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Latest procedure affecting product information:

II/0007/G

11/03/2024



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).

**VidPrevtyl Beta : EPAR - All authorised presentations****English (EN)** (90.38 KB - PDF)**First published:** 11/11/2022**Last updated:** 20/03/2024[View](#) [Other languages \(24\)](#) ▼**Product details****Name of medicine**

VidPrevtyl Beta

Active substance

SARS-CoV-2 prefusion Spike delta TM protein, recombinant (B.1.351 strain)

International non-proprietary name (INN) or common name

COVID-19 Vaccine (recombinant, adjuvanted)

Therapeutic area (MeSH)

COVID-19 virus infection

Anatomical therapeutic chemical (ATC) code

J07BN04

Pharmacotherapeutic group

Vaccines

Therapeutic indication

VidPrevtyl Beta is indicated as a booster for active immunisation to prevent COVID-19 in adults who have previously received an mRNA or adenoviral vector COVID-19 vaccine (see sections 4.2 and 5.1 in [product information document](#)).

The use of this vaccine should be in accordance with official recommendations.

Authorisation details**EMA product number**

EMA/H/C/005754

Marketing authorisation holder

Sanofi Pasteur

14 Espace Henry Vallée
69007 Lyon
France

Opinion adopted

10/11/2022

Marketing authorisation issued

10/11/2022

Withdrawal of marketing authorisation

18/03/2024

Revision

4

Assessment history

Changes since initial authorisation of
medicine



Initial marketing authorisation
documents



Safety updates

**COVID-19 vaccines - Safety update: 8
December 2022**

Reference Number: Rev. 2

English (EN) (239.73 KB - PDF)

First published: 08/12/2022

BioNTech-Pfizer Exhibit 1284

Last updated: 09/08/2024

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**VidPrevtyl Beta: Periodic safety update
report assessment 10 May 2023 to 9
November 2023**

English (EN) (7.97 MB - PDF)

First published: 30/07/2024

[View](#) 



**VidPrevtyl Beta: Periodic safety update
report assessment 10 November 2022 to
9 May 2023**

English (EN) (13.77 MB - PDF)

First published: 20/02/2024

Last updated: 20/03/2024

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News on VidPrevtyl Beta

[Meeting highlights from the Committee for Medicinal
Products for Human Use \(CHMP\) 7-10 November 2022](#)

11/11/2022

[EMA recommends approval of VidPrevtyl Beta as a COVID
19 booster vaccine](#)

10/11/2022

More information on VidPrevtyl Beta

BioNTech-Pfizer Exhibit 1284



Public statement on VidPrevtyl Beta: Withdrawal of the marketing authorisation in the European Union

Reference Number: EMA/585020/2023

English (EN) (122.74 KB - PDF)

First published: 20/03/2024

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More information on VidPrevtyl Beta

- [EMA-002915-PIP01-20-M01 - paediatric investigation plan](#)

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