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Decision

Regulatory approval of Pfizer/BioNTech vaccine for COVID-19

Information for healthcare professionals and the public about the Pfizer/BioNTech vaccine.

From:
Medicines and Healthcare products Regulatory Agency (/government/organisations/medicines-and-healthcare-products-regulatory-agency)

Published
2 December 2020

Last updated
24 May 2022 —

Applies to England, Scotland and Wales

Documents

Summary of Product Characteristics Comirnaty 30 micrograms/dose concentrate for age 12+ (purple cap) (/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-of-product-characteristics-for-covid-19-vaccine-pfizerbiontech)

HTML

Summary of Product Characteristics Comirnaty 30 micrograms/dose concentrate for age 12+ (purple cap) (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1071424/SPC_COMIRNATY_30_mcg_Purple_cap.pdf)

PDF, 1020 KB, 22 pages

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Patient Information Leaflet Comirnaty 30 micrograms/dose concentrate for age 12+ (purple cap) (/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/patient-information-leaflet-for-covid-19-vaccine-pfizerbiontech)

Related content

Collection

- MHRA guidance on coronavirus (COVID-19) (/government/collections/mhra-guidance-on-coronavirus-covid-19)

HTML

Patient Information Leaflet for Comirnaty 30 micrograms/dose concentrate for age 12+ (purple cap) (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1071425/PIL_COMIRNATY_30_mcg_Purple_cap.pdf)

PDF, 588 KB, 10 pages

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▶ Request an accessible format.

Summary of Product Characteristics for Comirnaty 10 micrograms/dose concentrate for ages 5-11 (orange cap) (/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-of-product-characteristics-for-covid-19-vaccine-pfizerbiontech-10-micrograms)

HTML

Summary of product characteristics for Comirnaty 10 micrograms/dose concentrate for ages 5-11 (orange cap) (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1077913/COMIRNATY10_TS_Orange_SmPC_CLEAN.pdf)

PDF, 924 KB, 23 pages

Patient Information Leaflet for Comirnaty 10 micrograms/dose concentrate for ages 5-11 (orange cap) (/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/patient-information-leaflet-for-covid-19-vaccine-pfizerbiontech-10-micrograms)

HTML

Patient Information Leaflet for Comirnaty 10 micrograms/dose concentrate for ages 5-11 (orange cap) (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1077917/COMIRNATY10_TS_Orange_PIL_CLEAN.pdf)

PDF, 713 KB, 11 pages

ARCHIVE: Information for Healthcare Professionals on COVID-19 Vaccine Pfizer/BioNTech (Regulation 174) (/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine)

HTML

ARCHIVE: Information for Healthcare Professionals on COVID-19 Vaccine Pfizer/BioNTech (Regulation 174) (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1043778/Temporary_Authorisation_HCP_Information_BNT162_19_0_UK_Clean.pdf)

PDF, 540 KB, 18 pages

ARCHIVE: Information for UK recipients on Pfizer/BioNTech COVID-19 vaccine (Regulation 174) (/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-uk-recipients-on-pfizerbiontech-covid-19-vaccine)

HTML

ARCHIVE: Information for UK recipients on COVID-19 Vaccine Pfizer/BioNTech (Regulation 174) (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1043779/Temporary_Authorisation_Patient_Information_BNT162_18_0_UK_Clean.pdf)

PDF, 130 KB, 5 pages

ARCHIVE: Conditions of Authorisation for COVID-19 Vaccine Pfizer/BioNTech (Regulation 174) (/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/conditions-of-authorisation-for-pfizerbiontech-covid-19-vaccine)

HTML

ARCHIVE: Conditions of Authorisation for COVID-19 Vaccine Pfizer/BioNTech (Regulation 174) (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1022642/Conditions_of_authorisation_for_Pfizer_BioNTech_vaccine__27_Sept.pdf)

PDF, 163 KB, 7 pages

Conditions of Authorisation for COVID-19 Vaccine Pfizer/BioNTech (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1071426/Comirnaty_GB_CMA_Conditions_270422.pdf)

PDF, 90.8 KB, 1 page

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▶ Request an accessible format.

Summary of the Public Assessment Report for COVID-19 Vaccine Pfizer/BioNTech (/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine)

HTML

Public Assessment Report for COVID-19 Vaccine Pfizer/BioNTech (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/997584/COVID-19_mRNA_Vaccine_BNT162b2__UKPAR___PFIZER_BIONTECH_ext_of_indication_11.6.2021.pdf)

PDF, 4.1 MB, 74 pages

Details

The 15-minute observation period following vaccination with COVID-19 Vaccine Pfizer/BioNTech or Moderna has been removed for individuals aged 12 years and over who have no history of a severe allergic reaction (as outlined in the Greenbook advice (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1057798/Greenbook-chapter-14a-28Feb22.pdf).) This follows careful review of the safety data by the MHRA and advice from the government's independent Commission on Human Medicines. A temporary suspension of the 15-minute observation period for children aged 5-11 years remains in place and this will be reviewed on a regular basis.

There are three presentations of the COVID-19 Vaccine Pfizer/BioNTech authorised for use in Great Britain, two of which are currently available:

- The original 30 microgram/dose presentation which needs to be diluted (purple cap)
- The 10 microgram/dose paediatric presentation currently for 5-11 year-olds, which also needs to be diluted (orange cap)

The product information for the above two presentations can be found on this page.

There is currently no GB supply of the third presentation and the product information for this will only be published once this supply becomes available.

All three presentations use the same drug substance but have specific administration requirements and are differentiated by use of different coloured caps on the vials.

Initially, the COVID-19 Vaccine Pfizer/BioNTech was supplied in the UK on a temporary basis under Regulation 174 of the Human Medicine Regulations 2012, but this was always intended to be a temporary arrangement. Supply of the vaccine is now in accordance with the conditional Marketing Authorisation (CMA) with all remaining Regulation 174 stocks expiring at the end of February 2022.

The product information for the COVID-19 Vaccine Pfizer/BioNTech authorised under Regulation 174 can also be found on this page although.

The original CMA was issued by the European Medicines Agency (EMA) on 21 December 2020 and was automatically converted to a GB CMA on 1 January 2021. The CMA issued by the EMA has continued to have effect in Northern Ireland since 21 December 2020.

The information for healthcare professionals and UK recipients on using the vaccine safely has been updated as new data have become available and this will continue under the CMA. Please regularly check this information as it is often updated.

The MHRA regularly publishes (https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting) reports of the safety of the COVID-19 vaccines.

Published 2 December 2020
Last updated 24 May 2022 + show all updates

1. 24 May 2022
   Updated SpC and PIL for orange cap product (Comirnaty 10 micrograms/dose Concentrate for Dispersion for Injection - Shelf-life information updated.
2. 5 May 2022
   The website decision page for the mRNA COVID-19 vaccines has been updated to reflect the fact that the 15-minute observation period following vaccination has been removed for individuals aged 12 years and over who have no history of a severe allergic reaction.
3. 27 April 2022
   Updated information to Summary of Product Characteristics and Patient Information Leaflets (Purple Cap and Orange Cap)
4. 13 April 2022
   Updated shelf life from 9-months to 12-months for Comirnaty 30 microgram COVID-19 mRNA Vaccine (purple cap). Updated SmPC and PIL.
5. 25 March 2022
   Updated 30 micrograms and 10 micrograms PIL and SPC.
6. 14 March 2022
   PIL and SMPC Comirnaty 10 micrograms/dose concentrate: updated title to include reference to orange cap. Updated the shelf life life from 6 months to 9 months. SMPC and PIL Comirnaty 30 micrograms/dose concentrate: Updated title to include reference to purple cap. Includes new reference to the fact there is now paediatric formulation available for children 5 to 11 years of age. Myo/pericarditis changed from a potential side effect of unknown frequency to "very rare". Erythema multiforme added as a potential side effect with unknown frequency. Wording around shelf life updated.
7. 24 December 2021
   Information for Healthcare Professionals and UK recipients on COVID-19 Vaccine Pfizer/BioNTech (Regulation 174) was updated
8. 22 December 2021

Added HTML document for Summary of product characteristics for Comirnaty 10 micrograms/dose concentrate for dispersion for injection

9. 22 December 2021
   Added Patient Information Leaflet and Summary of Product Characteristics for COVID-19 Vaccine Pfizer/BioNTech 10 micrograms
10. 14 December 2021
    Banner added to main page: The 15 minute observation period following a vaccination with Pfizer/BioNTech or Moderna will be temporarily suspended as part of measures to increase the booster rollout. Regulatory documents remain unchanged.
11. 3 December 2021
    The Pfizer/BioNTech vaccine (Comirnaty) Conditional Marketing Authorisation has been renewed: changes to the SmPC – section 9 and section 10.
12. 15 November 2021
    Updated sections of the Summary of Product Characteristics and Patient Information Leaflet for COVID-19 Vaccine Pfizer/BioNTech (Conditional Marketing Authorisation documents) to include information about receiving a 3rd/booster dose. Also to include two new reagents, Sodium Hydroxide and Hydrochloric Acid, which are used in small quantities during the preparation of one of the solutions used in the manufacturing process. The official International non-proprietary name ‘tozinameran’ has also been added.
13. 28 October 2021
    Updated figures in HCP information Table 5: Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2 – participants without evidence of infection and with or without evidence of infection prior to 7 days after Dose 2 – adolescents 12 to 15 years of age evaluable efficacy (7 days) population
14. 27 October 2021
    Update to the summary of product characteristics and patient information leaflet for the Pfizer/BioNTech vaccine condition marketing authorisation documents
15. 27 October 2021
    Updated for both HCPs and public
16. 27 September 2021
    Extended vaccine shelf life from 6 months to now 9 months.
17. 9 September 2021
    Updated sections of Information for Healthcare Professionals on COVID-19 Pfizer/BioNTech (Regulation 174) and Information for UK recipients on COVID-19 Vaccine Pfizer/BioNTech (Regulation 174) to include information about receiving a third dose. Also updated the Regulation 174 Conditions document with an additional pharmacovigilance condition.
18. 11 August 2021
    Updates to the Conditional Marketing Authorisation SmPC and PIL and updates to the Regulation 174 Information for Healthcare Professionals and Information for recipients
19. 2 August 2021
    Updated conditions of authorisation for Pfizer BioNTech vaccine
20. 9 July 2021
    We have published the Summary of Product Information, Patient Information Leaflet and Conditions document for the GB Conditional Marketing Authorisation of the Pfizer/BioNTech vaccine.
21. 28 June 2021
    Updated the Public Assessment report, to reflect the extension to the current UK approval of the Pfizer/BioNTech COVID-19 vaccine that allows its use in 12- to 15-year-olds, as announced on 4 June 2021.
22. 25 June 2021
    Added a warning on myocarditis to the Information for UK recipients and the Information for Healthcare Professionals
23. 4 June 2021
    Updated Conditions of Authorisation, Information for Healthcare Professionals and Information for UK Recipients documents in line with an extension to the current UK approval of the Pfizer/BioNTech COVID-19 vaccine that allows its use in 12- to 15-year-olds.
24. 20 May 2021
    Updated the Information for Healthcare Professionals, Information for UK recipients and Conditions of Authorisation documents. This is to reflect a change that once removed from the freezer, the undiluted vaccine has a maximum shelf life of up to 1 month (31 days). This was previously 5 days.
25. 31 March 2021
    Published new versions of the Conditions of Authorisation documents, with an additional clause in the Deployment section relating to transfers of frozen vials stored at ultra-low temperature and handling of temperature excursions
26. 9 March 2021
    Added information on fevers to Section 4 of Information for UK Recipients and section 4.8 of Information for Healthcare Professionals.
27. 28 January 2021
    Published new versions of the Conditions of Authorisation documents, with an additional clause relating to off-label prescribing
28. 26 January 2021
    We have updated the Product Information to state that the vaccine is manufactured with enough volume for six doses, if our latest guidance for Healthcare Professionals is followed.

29. 31 December 2020
    Updated HTML and PDF attachments for 'Conditions of authorisation for Pfizer BioNTech'
30. 30 December 2020
    Updated the Information for UK recipients and the Information for healthcare professionals documents, to reflect changes to the dosage interval, advice for women who are pregnant or breastfeeding and to those with allergies.
31. 24 December 2020
    Updated guidance for Healthcare Professionals on obtaining a sixth dose from a vial.
32. 16 December 2020
    Added an accessible HTML document: Summary of the Public Assessment Report
33. 15 December 2020
    Added the Public Assessment Report for the Pfizer/BioNTech COVID-19 vaccine
34. 10 December 2020
    Changes to section 4.2 and 6 of the Information for UK Healthcare Professionals to provide clarification following further feedback and update to section 4.4 to strengthen information on special warnings and precautions for use. Changes to warnings and precautions and clarification in section 6 of the Information for UK Recipients.
35. 8 December 2020
    Accessible HTML versions of both the 'Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine' and the 'Information for UK recipients on Pfizer/BioNTech COVID-19 vaccine' are now available.
36. 3 December 2020
    A note regarding the ingredients has been added as well as an accessible HTML version of 'Conditions of Authorisation for Pfizer/BioNTech COVID-19 vaccine'. A reference to the Medicines Act 1968 has been corrected.
37. 2 December 2020
    Added new document: Conditions of Authorisation for Pfizer BioNTech COVID-19 vaccine.
38. 2 December 2020
    First published.

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