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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.

Published 2 December 2020

Last updated 24 December 2020 — see all updates

From:

Medicines and Healthcare products Regulatory Agency (<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>)

Documents

Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine (<https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine>)

HTML

Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948101/Temporary_Authorisation_HCP_Information.pdf)

PDF, 395KB, 11 pages

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Information for UK recipients on Pfizer/BioNTech COVID-19 vaccine (<https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-uk-recipients-on-pfizerbiontech-covid-19-vaccine>)

HTML

Information for UK recipients on Pfizer/BioNTech COVID-19 vaccine
(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/943249/Information_for_UK_recipients.pdf)

PDF, 123KB, 5 pages

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Conditions of Authorisation for Pfizer/BioNTech COVID-19 vaccine
(<https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/conditions-of-authorisation-for-pfizerbiontech-covid-19-vaccine>)

HTML

Conditions of Authorisation for Pfizer/BioNTech COVID-19 vaccine
(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940975/Conditions_of_Authorisation_for_Pfizer_BioNTech_vaccine.pdf)

PDF, 159KB, 5 pages

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Public Assessment Report for Pfizer/BioNTech COVID-19 vaccine
(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/944544/COVID-19_mRNA_Vaccine_BNT162b2_UKPAR_PFIZER_BIONTECH_15Dec2020.pdf)

PDF, 2.39MB, 51 pages

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Summary of the Public Assessment Report for Pfizer/BioNTech COVID-19 vaccine (<https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine>)

HTML

Details

Information about the COVID-19 vaccine, approved by MHRA on 2 December 2020.

The Information for healthcare professionals document is a description of a medicinal product's properties and the conditions attached to its use. It explains how to use and prescribe a medicine. It is used by healthcare professionals, such as doctors, nurses and pharmacists.

The Information for UK recipients document provides information for patients on using the medicine safely. This is based on the Information for healthcare professionals of the product.

The public assessment report is a scientific report, written by the MHRA. 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.

Find out more about the approval from our press release (<https://www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine>).

Ingredients

The Medicines and Healthcare products Agency (<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>) can confirm that the Pfizer/BioNTech COVID-19 vaccine does not contain any components of animal origin.

A full list of ingredients for the qualitative and quantitative composition of the vaccine can be found at point 2 in the Information for Healthcare Professionals on Pfizer/BioNtech Vaccine (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940565/Information_for_Healthcare_Professionals_on_Pfizer_BioNtech_COVID-19_vaccine.pdf).

A full list of ingredients for the excipient composition of the vaccine can be found at point 6 in the Information for Healthcare Professionals on Pfizer/BioNtech Vaccine (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940565/Information_for_Healthcare_Professionals_on_Pfizer_BioNtech_COVID-19_vaccine.pdf).

A full list of ingredients for the qualitative and quantitative composition of the vaccine and a full list of the excipient composition of the vaccine can be found at point 6 in the Information for Recipients of the Pfizer/BioNtech Vaccine (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940566/Information_for_UK_recipients_on_Pfizer_BioNtech_COVID-19_vaccine.pdf).

Published 2 December 2020

Last updated 24 December 2020 + show all updates

1. 24 December 2020

Updated guidance for Healthcare Professionals on obtaining a sixth dose from a vial.

2. 16 December 2020

Added an accessible HTML document: Summary of the Public Assessment Report

3. 15 December 2020

Added the Public Assessment Report for the Pfizer/BioNtech COVID-19 vaccine

4. 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.

5. 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.

6. 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.

7. 2 December 2020

Added new document: Conditions of Authorisation for Pfizer BioNTech COVID-19 vaccine.

8. 2 December 2020

First published.

Brexit transition

06 days to go

Check you're ready for 2021

(<https://www.gov.uk/transition>)

Related content

Collection

- MHRA guidance on coronavirus (COVID-19) (<https://www.gov.uk/government/collections/mhra-guidance-on-coronavirus-covid-19>)

Explore the topic

- Pharmacy (<https://www.gov.uk/health-and-social-care/pharmacy>)
- Vaccinations for coronavirus (<https://www.gov.uk/coronavirus-taxon/vaccinations>)