28 January 2021
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COVID-19 vaccine safety update for Comirnaty: 28 January 2021

Marketing authorisation holder: BioNTech Manufacturing GmbH

Key Messages

The latest safety data for this vaccine are in line with the known side effect profile, and the related reviews are presented in this update.

Reports of suspected severe allergic reaction have not identified new aspects regarding the nature of this known side effect.

No specific safety concern has been identified for vaccine use in frail elderly individuals.

The benefits of Comirnaty in preventing COVID-19 continue to outweigh any risks, and there are no recommended changes regarding the use the vaccine.

Safety updates provide the outcomes of the assessment of emerging data since marketing authorisation for COVID-19 vaccines. The assessments are carried out by EMA's safety committee (Pharmacovigilance Risk Assessment Committee (PRAC)). The safety updates are published regularly at Post-authorisation: Safety updates.

All published safety updates for Comirnaty are available at Comirnaty: safety updates.

1. Updates on safety of Comirnaty

On 28 January 2021, PRAC concluded that the safety data reviewed for Comirnaty are in line with the vaccine's known benefit-risk profile. The review covered all new safety data emerging since 21 December 2020, including the first Summary Monthly Safety Report[1] from the marketing authorisation holder. Specifically, the following was concluded by PRAC in relation to:

[1] Summary Monthly Safety Reports will be compiled by the marketing authorisation holders for COVID-19 vaccines to support timely and continuous benefit-risk evaluations. The submission of such reports complements the submission of periodic safety update reports (PSURs).

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Severe allergic reaction (anaphylaxis)

Anaphylaxis is a known side effect of Comirnaty. The assessment of the reports of suspected anaphylaxis to date did not identify new aspects regarding the nature of this side effect. PRAC noted that a recent analysis in the United States estimated the frequency of anaphylaxis as approximately 11 cases per million doses of Comirnaty administered[2]. A frequency estimate appropriate for the EU product information could not yet be determined.

PRAC requested the marketing authorisation holder to continue reviewing all anaphylaxis cases for further assessment by the committee.

Information on managing the risk of anaphylaxis is already available in the product information.

Review of reports of suspected side effects with fatal outcome, specifically in frail elderly individuals

Given concerns which arose from Norway about deaths reported in frail elderly individuals after vaccination with Comirnaty, PRAC reviewed the current reports of suspected side effects with fatal outcome in individuals of any age. This review did not suggest a safety concern.

In many cases concerning individuals above 65 years of age, progression of (multiple) pre-existing diseases seemed to be a plausible explanation for death. In some individuals, palliative care had already been initiated before vaccination.

Before Comirnaty was granted a marketing authorisation in the EU, the safety of the vaccine was carefully assessed through large clinical trials across age groups including study participants that were 75 years of age and older, as detailed in the public assessment report.

PRAC concluded that based on the current data there was no need to amend the product information regarding how Comirnaty should be used, including in frail elderly individuals. PRAC requested that the marketing authorisation holder continues reviewing all reports of suspected side effects with fatal outcome thoroughly.

2. Other information for Comirnaty

Comirnaty is a vaccine that has been authorised in the European Union (EU) for use in people aged 16 years and older to protect against developing COVID-19 when infected with the coronavirus SARS-CoV-2. COVID-19 is a potentially severe disease that may result in death.

Comirnaty contains a molecule called mRNA, which the body uses to temporarily produce the SARS-CoV-2 spike protein. The mRNA is broken down shortly after vaccination. The spike protein does not cause COVID-19.

Before Comirnaty was granted a marketing authorisation in the EU, the efficacy and safety of the vaccine was assessed through pre-clinical studies and large clinical trials. More than 18,000 participants have been given the vaccine in clinical trials.

[2] Centres for Disease Control and Prevention (CDC) COVID-19 Response Team, Food and Drug Administration: Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine: United States, December 14–23, 2020. MMWR. 2021; 70 (2): 46-52 (epub 6 Jan 2021).

The most common side effects known for Comirnaty will not be experienced by everybody, are usually mild or moderate, and get better within a few days after vaccination.

More information on how Comirnaty works and its use is available in the medicine overview for Comirnaty. This includes information on use in pregnant and breastfeeding women and immunocompromised individuals.

Information in all EU/EEA languages is available in the product information, which includes the summary of product characteristics and the package leaflet.

3. How safety is monitored

As for all COVID-19 vaccines, all relevant new information emerging on Comirnaty is collected and promptly reviewed. This is in line with the pharmacovigilance plan for COVID-19 vaccines of the EU regulatory network.

Collecting suspected side effects

The EU regulatory network continuously monitors reports of suspected side effects observed in vaccinated individuals. These reports are collected and recorded in EudraVigilance, a system operated by EMA for managing and analysing information on suspected adverse reactions to medicines.

Vaccinated individuals and healthcare professionals should report suspected side effects via the national reporting systems. For more information, see Reporting side effects. Information on how to report side effects in your Member State is available in the package leaflet and the list of national competent authorities.

You may visit EudraVigilance – European database of suspected drug reaction reports and search for "COVID-19 mRNA Vaccine PFIZER-BIONTECH (Tozinameran)" to see all suspected side effects reported for Comirnaty in the EU. Please note that these reports describe suspected side effects in individuals, i.e. these events may not necessarily have been caused or otherwise be related to the vaccine.

Planned and ongoing studies

The company that markets Comirnaty will continue to provide results from the main clinical trial, which is ongoing for up to two years, and conduct additional studies to monitor the safety and effectiveness of the vaccine as it is used in the vaccination campaigns and other clinical practice. For the list of planned or ongoing safety studies for Comirnaty, see the risk management plan.

A paediatric investigation plan (PIP) for Comirnaty is in place. This describes how the company will collect data on the vaccine's efficacy and safety for its potential use in children.

In addition, EMA and European authorities are coordinating observational studies in EU Member States looking at real-world data from clinical practice to monitor the safety and effectiveness of COVID-19 vaccines, including in pregnant women. For more details on the ongoing projects, see Treatments and vaccines for COVID-19: post-authorisation.