



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 March 2021

COVID-19 vaccine safety update

COMIRNATY

BioNTech Manufacturing GmbH

The latest safety data for this vaccine are in line with the known benefit-risk profile; the outcomes of the related assessments are presented in this update.

Diarrhoea and vomiting after vaccination have been identified as new side effects.

The benefits of Comirnaty in preventing COVID-19 continue to outweigh any risks, and there are no recommended changes regarding the use of this 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]) based on all available data. The safety updates are published regularly at [Post-authorisation: Safety updates](#).

All published safety updates for Comirnaty are available at [Comirnaty: safety updates](#).

This safety update follows the last update of 28 January 2021.

1. Updates on safety of Comirnaty

On 25 February 2021, after assessing new safety data, PRAC concluded that the benefit-risk balance of Comirnaty remains unchanged. The assessment covered all new safety data emerging worldwide, including the second Summary Monthly Safety Report¹ and a review of severe allergic reaction from the marketing authorisation holder. Specifically, the following was concluded by PRAC in relation to:

Diarrhoea and vomiting

The assessment identified diarrhoea and vomiting after vaccination as new side effects of Comirnaty. The frequency of these side effects and the extent to which they occur are being assessed further. The product information will be updated accordingly.

Severe allergic reaction (anaphylaxis)

Case reports of suspected anaphylaxis for Comirnaty were assessed and did not lead to any changes in the recommended use of this vaccine. Anaphylaxis continues to be closely monitored. Information on the clinical management of anaphylaxis is already available in the [product information](#).

Suspected side effects with fatal outcome

PRAC assessed case reports of suspected side effects with fatal outcome following vaccination with Comirnaty. In most cases, progression of (multiple) pre-existing diseases seemed to be a plausible explanation for death. In some individuals, palliative care had been initiated before vaccination. This assessment of the available data did not identify a safety concern.

2. Other information for Comirnaty

Comirnaty is a vaccine that was authorised in the European Union (EU) on 21 December 2020 for use in people aged 16 years and older to prevent development of 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

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).

down shortly after vaccination. The spike protein does not cause COVID-19.

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

Like all medicines, this vaccine can cause side effects, although not everybody will experience them. The most common side effects known for Comirnaty 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](#). 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 (comprising the regulatory bodies of the EU Member States, EMA and the European Commission).

Collecting case reports of suspected side effects

The EU regulatory network continuously monitors reports of suspected side effects observed in vaccinated individuals. These case reports are collected and recorded in [EudraVigilance](#), a system operated by EMA for managing and analysing information on suspected side effects of medicines.

Vaccinated individuals and healthcare professionals should report suspected side effects via the national reporting systems, which also contribute to EudraVigilance. 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 by, or be otherwise 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. It will also conduct additional studies to monitor the safety and effectiveness of the vaccine as it is used in vaccination campaigns and other clinical practice. For the list of planned and 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 is 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.

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