14 April 2021

COVID-19 vaccine safety update

COMIRNATY

BioNTech Manufacturing GmbH

Specific allergic skin reactions will be added to the product information.

There are no recommended changes to the product information regarding how to use this vaccine; Comirnaty is effective in preventing COVID-19.

Safety updates provide information about the assessments of emerging worldwide 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 COVID-19 vaccines: authorised.

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

This safety update follows the last update of 29 March 2021.

Since the marketing authorisation in the European Union (EU) on 21 December 2020 until 9 April 2021, more than 60 million doses of Comirnaty have been administered in the EU/EEA[1].

[1] The European Centre for Disease Prevention and Control (ECDC) collects these data from EU Member States as well as from the additional countries of the European Economic Area (EEA) Norway, Iceland and Liechtenstein.

1. Updates on safety of Comirnaty

At its meeting held 6 to 9 April 2021, PRAC assessed the following in relation to:

Hypersensitivity reactions

Based on data from clinical trials and use in vaccination campaigns, PRAC requested the addition of the following hypersensitivity reactions (allergic reactions) to the product information of Comirnaty: skin rash and pruritus (itching of the skin) as uncommon side effects (occurring in less than 1 in 100 persons), and urticaria (raised, red and itchy skin rash) and angioedema (rapid swelling under the skin) as rare side effects (occurring in less than 1 in 1,000 persons).

2. Other information for Comirnaty

Comirnaty is a vaccine that was authorised in the EU for use in people aged 16 years and older to prevent 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 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, 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 suspected side effects. Information on how to report in your Member State is available in the package leaflet and via 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/EEA. 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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