29 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.

Swelling of the vaccinated limb usually recovers by itself.

The benefits of Comirnaty in preventing COVID-19 continue to outweigh the 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]). 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 4 March 2021.

Since the marketing authorisation in the European Union (EU) on 21 December 2020 until 25 March 2021, more than 45 million doses of Comirnaty have been administered in the EU/EEA[1].

1. Updates on safety of Comirnaty

On 25 March 2021, PRAC assessed all new safety data emerging worldwide, including the latest Summary Monthly Safety Report[2] from the marketing authorisation holder, and concluded that the benefit-risk balance of Comirnaty remains positive.

Specifically, the following was concluded by PRAC in relation to:

Extensive swelling of the vaccinated limb

The assessment identified extensive swelling of the vaccinated limb, usually the upper arm, as a new side effect of Comirnaty. Although such swelling may appear severe to the vaccinated person, this condition usually recovers by itself within a couple of days after vaccination. The frequency of this side effect is being assessed further. The product information will be updated accordingly.

Localised swelling in persons with history of dermal filler injections

PRAC started an assessment of some reports of localised swelling after vaccination with Comirnaty in people with a history of injections with dermal fillers (gel-like substances injected under the skin). PRAC requested the marketing authorisation holder to review all cases and the scientific literature for further assessment by the committee[3].

Diarrhoea and vomiting

The frequency of the recently identified side effects diarrhoea and vomiting have now been estimated as very common (i.e. occurring in more than 1 in 10 vaccinated persons) and common (i.e. occurring in

[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.
[2] Summary Monthly Safety Reports will be compiled by the marketing authorisation holders for COVID-19 vaccines to support timely and continuous benefit-risk evaluations. These reports complement the submission of Periodic Safety Update Reports (PSURs).
[3] See Meeting Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 March 2021.

more than 1 in 100 vaccinated persons), respectively. The product information of Comirnaty will be updated accordingly.

Immune thrombocytopenia (ITP)

For all COVID-19 vaccines used in the EU, a specific PRAC assessment of immune thrombocytopenia (ITP, low blood platelet levels that can lead to bruising and bleeding) as a suspected side effect is ongoing[4].

The PRAC assessment of the ITP cases reported to EudraVigilance (see section 3) for Comirnaty from vaccination campaigns did not reveal a pattern confirming a causal relationship of ITP with Comirnaty. In some cases, the time-to-onset of symptoms was inconsistent with the possibility of a vaccine-mediated immune reaction.

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.

[4] See Meeting Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 March 2021.

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 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/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.

By 22 March 2021, 94 303 cases of suspected side effects reported for Comirnaty from the EU/EEA had been included and monitored in EudraVigilance, relating to around 42 million doses administered[5].

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.

[5] See EMA Public stakeholder meeting: approval, safety monitoring and impact of COVID-19 vaccines in the EU on 26 March 2021

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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