



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 May 2021

# COVID-19 vaccine safety update

## COMIRNATY

BioNTech Manufacturing GmbH

Swelling of the face in people who have had a dermal filler injection will be added to the product information of Comirnaty as a side effect.

Case reports of inflammation of the heart muscle and membrane will be further assessed.

Comirnaty is effective in preventing COVID-19.

This safety update follows the last update of 14 April 2021.

Safety updates provide information about the assessments of emerging worldwide safety data since marketing authorisation for COVID-19 vaccines. Safety assessments are carried out primarily by EMA's [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](#).

Since the marketing authorisation in the European Union (EU) on 21 December 2020 until 6 May 2021, almost 110 million doses of Comirnaty have been administered in the EU/EEA<sup>1</sup>.

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## 1. Updates on safety of Comirnaty

At its meeting held 3 to 6 May 2021, based on new safety data including the latest Monthly Summary Safety Report (MSSR)<sup>2</sup> from the marketing authorisation holder, PRAC assessed the following:

### Localised swelling of the face in persons with history of dermal filler injections

PRAC assessed cases of localised swelling reported with Comirnaty in people with a history of injections with dermal fillers (gel-like substances injected under the skin), together with information from the scientific literature and further available evidence.

Given the reported location of the swellings, time to onset (median: 2 days) and an overall biological plausibility of a causal relationship with the vaccine, PRAC concluded that the product information for Comirnaty should be updated. It will include swelling of the face as a side effect that may occur in vaccine recipients who have had an injection of dermal fillers<sup>3</sup>.

### Myocarditis and pericarditis

EMA is aware of cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) reported following vaccination with Comirnaty. There is no indication at the moment that these cases are due to the vaccine. However, PRAC has requested the marketing authorisation holder to provide further detailed data, including an analysis of the cases according to age and gender, in the context of the next MSSR and will consider if other regulatory action is needed<sup>4</sup>.

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<sup>1</sup> 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.

<sup>2</sup> Monthly Summary Safety Reports, also referred to as pandemic summary safety reports, will be compiled by the marketing authorisation holders to support timely and continuous benefit-risk evaluations for COVID-19 vaccines used during the pandemic. These reports complement the submission of [Periodic Safety Update Reports \(PSURs\)](#).

<sup>3</sup> See [Meeting Highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 3-6 May 2021](#)

<sup>4</sup> See [Meeting Highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 3-6 May 2021](#)

## 2. Other information for Comirnaty

Comirnaty is a vaccine that was authorised in the EU on 21 December 2020 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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