



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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# COVID-19 vaccine safety update

## COMIRNATY

BioNTech Manufacturing GmbH

Reports of inflammation of the heart muscle (myocarditis) and membrane (pericarditis) in a small number of people after vaccination continue to be assessed under an accelerated timetable.

There are no updates to the product information.

Comirnaty is effective in preventing COVID-19.

This safety update follows the last update of 11 May 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 its marketing authorisation in the European Union (EU) on 21 December 2020 until 10 June 2021, more than 196 million doses of Comirnaty have been administered in the EU/EEA<sup>1</sup>.

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## 1. Updates on safety of Comirnaty

Based on new safety data, including the latest Monthly Summary Safety Report (MSSR)<sup>2</sup> from the marketing authorisation holder and data reported by patients and healthcare professionals to EudraVigilance (see section 3), PRAC assessed the following at its meeting held 7 to 10 June 2021:

### Myocarditis and pericarditis

PRAC is continuing its assessment of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) reported in a small number of people following vaccination with COVID-19 vaccines. This assessment follows case reports of myocarditis/pericarditis after vaccination with Comirnaty in Israel, as presented in the Comirnaty safety update of May 2021<sup>3</sup>. The cases mainly concerned males under 30 years of age, with symptoms mostly starting within several days of vaccination with the second dose. Most of these cases were mild and resolved within a few days<sup>4</sup>.

In total, 122 cases of myocarditis and 126 cases of pericarditis had been reported from the EU/EEA to EudraVigilance with Comirnaty by the end of May 2021, at which time around 160 million doses of Comirnaty had been administered in the EU/EEA. Cases reported to EudraVigilance concern suspected side effects, i.e. medical events that have been observed after vaccination, but which are not necessarily related to or caused by the vaccine.

Currently, further analysis is needed to conclude whether there is a causal relationship between myocarditis/pericarditis and COVID-19 vaccines, and PRAC has requested additional data from the companies marketing the vaccines.

PRAC encourages all healthcare professionals and patients to report any cases of myocarditis or pericarditis and other adverse events occurring in people after vaccination.

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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 [safety update for Comirnaty of 11 May 2021](#)

<sup>4</sup> See [press release of the Ministry of Health in Israel of 2 June 2021](#)

For Comirnaty and COVID-19 Vaccine Moderna, PRAC is conducting the assessment under an accelerated timetable, and finalisation is expected in July 2021.

Myocarditis and pericarditis are inflammatory diseases of the heart that can occur following infections or immune diseases. Depending on the data source, the incidence estimates for myocarditis and pericarditis in the general (unvaccinated) EU/EEA population prior to the COVID-19 pandemic range from 1 to 10 in 100,000 people per year. Symptoms of myocarditis and pericarditis can vary but often include shortness of breath, a forceful heartbeat that may be irregular and chest pain. The conditions usually improve on their own or with treatment. Patients who have such symptoms should consult their doctor<sup>5</sup>.

## 2. Other information for Comirnaty

Comirnaty is a vaccine that was authorised in the EU on 21 December 2020 to prevent COVID-19 when infected with the coronavirus SARS-CoV-2. The initial marketing authorisation was for use in people aged 16 years and older; on 31 May 2021, the marketing authorisation was extended to use in individuals aged 12 years and older. 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 all EU/EEA languages in the [medicine overview](#). This includes information on use in pregnant and breastfeeding women and immunocompromised individuals.

The full [product information](#) with the summary of product characteristics and the package leaflet is also available in all EU/EEA languages.

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<sup>5</sup> See [EMA public health communication on myocarditis and pericarditis with COVID-19 vaccines of 11 June 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 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](#) in all EU/EEA languages 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.

## European Medicines Agency

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

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**Telephone** +31 (0)88 781 6000

