03-September-2021

accessopa@libero.it

Your medical information enquiry concerning COMIRNATY▼ (COVID-19 mRNA vaccine (BNT162))

Dear Dr Stefanelli

Thank you for your enquiry regarding our medicine COMIRNATY▼.

▼ Relevant to member states of the EU and the European Economic Area (including Norway, Liechtenstein and Iceland): This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

Comirnaty has been authorised under a “conditional approval” scheme. The European Medicines Agency will review new information on this medicinal product at least every year and the Summary of Product Characteristics will be updated as necessary.

In response to your question on the safety profile and long-term safety of Comirnaty (COVID-19 mRNA Vaccine), please refer to the medical information response document enclosed entitled:

- **Undesirable Effects and General Safety**

In addition, the following information concerning clinical safety of Comirnaty, may also be of relevance:

European Public Assessment Report

The European Public Assessment Report (EPAR) for Comirnaty (COVID-19 mRNA Vaccine) published by the European Medicines Agency (EMA) provides additional data on the clinical safety of Comirnaty based on clinical trial data submitted to the EMA. The following information is included in the EPAR: [2][3]

Long term safety data is not available at this stage, however the Phase 2/3 study will follow the included subjects up to 2 years post vaccination, so these data are expected post-authorisation. [2]

2.5.2. Conclusions on clinical safety

The long-term safety of BNT162b2 mRNA vaccine is unknown at present, however further safety data are being collected in ongoing Study C4591001 for up to 2 years following administration of dose 2 of BNT162b2 mRNA vaccine in all age groups. Additionally, active surveillance studies are planned to follow long-term safety in vaccine recipients. [3]

For complete information, please refer to the EPAR via the following links:

- https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf

- https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-ii-0030-epar-assessment-report-variation_en.pdf

European Medicines Agency

What measures are being taken to ensure the safe and effective use of Comirnaty?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Comirnaty have been included in the Summary of Product Characteristics and the Package Leaflet. [4]

A risk management plan (RMP) for Comirnaty is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimise any potential risks. [4]

Safety measures will be implemented for Comirnaty in line with the EU safety monitoring plan for COVID-19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets Comirnaty will provide monthly safety reports. [4]

As for all medicines, data on the use of Comirnaty are continuously monitored. Suspected side effects reported with Comirnaty are carefully evaluated and any necessary action taken to protect patients. [4]

Further information and access to all **safety updates for Comirnaty** are available via the following link:
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty#safety-updates-section

In response to your second question concerning Comirnaty and possible impact on genetic material, please consider the information below from the United States Centers for Disease Control and Prevention (CDC) webpage "Myths and Facts about COVID-19 Vaccines": [2]

"Will a COVID-19 vaccine alter my DNA?

No. COVID-19 vaccines do not change or interact with your DNA in any way. Both mRNA and viral vector COVID-19 vaccines deliver instructions (genetic material) to our cells to start building protection against the virus that causes COVID-19. However, the material never enters the nucleus of the cell, which is where our DNA is kept." [5]

In response to your query concerning Comirnaty (COVID-19 mRNA Vaccine), and the possible administration of a 3 additional dose, and if this should be administrated to obtain a longer protection from the virus, we have pleasure in providing the following information:

PRESCRIBING INFORMATION

The Summary of Product Characteristics for Comirnaty (COVID-19 mRNA Vaccine) provides the following information of relevance: [1]

Section 4.2 Posology and method of administration

Posology

Individuals 12 years of age and older
Comirnaty is administered intramuscularly after dilution as a course of 2 doses (0.3 mL each). It is recommended to administer the second dose 3 weeks after the first dose. [1]

Section 4.4 Special warnings and precautions for use

Duration of protection
The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials. [1]

Limitations of vaccine effectiveness
As with any vaccine, vaccination with Comirnaty may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of vaccine. [1]

Comirnaty (COVID-19 mRNA Vaccine) is currently not authorized for administration of more than 2 doses. Pfizer does not suggest or recommend the use of Comirnaty in any manner other than as described in the Prescribing Information. [1]

For further information regarding this vaccine, please refer to the Comirnaty Summary of Product Characteristics.[1]

To further assist with your inquiry, please find also attached the following medical information documents which we hope will be of use:

- ***Administration of More Than a 2-Dose Series***
- ***Antibody Persistence and Duration of Immunity***

In response to your query concerning Comirnaty (COVID-19 mRNA Vaccine), and the duration of the protection after receiving the 2 dose and percentage of protection from the virus, we have pleasure in providing the following information:

PRESCRIBING INFORMATION

The Summary of Product Characteristics for Comirnaty (COVID-19 mRNA Vaccine) provides the following information of relevance: [1]

Section 4.4 Special warnings and precautions for use

Duration of protection
The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials. [1]

Limitations of vaccine effectiveness
As with any vaccine, vaccination with Comirnaty may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of vaccine. [1]

Section 5.1 Pharmacodynamic properties

Efficacy in participants 16 years of age and older

[…] Efficacy of COVID-19 mRNA Vaccine in preventing first COVID-19 occurrence from 7 days after Dose 2 compared to placebo was 94.6% (95% confidence interval of 89.6% to 97.6%) in participants 16 years of age and older with or without evidence of prior infection with SARS-CoV-2. [1]

For further information regarding this vaccine, please refer to the COMIRNATY Summary of Product Characteristics.[1]

To further assist with your inquiry, please find also attached the following medical information document which we hope will be of use:

- ***Antibody Persistence and Duration of Immunity***
- **Effectiveness in the Prevention of COVID-19**

Are there official recommendations on the COVID-19 vaccination programme?

The use of Comirnaty vaccine should be in accordance with official recommendations.[1] For official recommendations on the COVID-19 vaccination programme in Italy, please refer to the following website: https://www.aifa.gov.it/comirnaty

Please note that Pfizer is independent of these recommendations.

Pfizer is unable to make any dosage or treatment recommendations for individual patients; clinical judgement based on the medical history and the clinical status of a specific patient should dictate the appropriate actions to be taken.

REFERENCES

[1] Comirnaty (COVID-19 mRNA Vaccine). Summary of Product Characteristics (centralized license), applicable to all countries in the EU and Norway [V: Date of revision of text 07/2021 superseded 22 July 2021; LC].
[2] Comirnaty (COVID-19 mRNA Vaccine). European Public Assessment Report (EPAR). Available online at: https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf (Accessed on September 02, 2021).
[3] Comirnaty (COVID-19 mRNA Vaccine). European Public Assessment Report (EPAR). EMEA/H/C/005735/II/0030. Available from: Comirnaty, INN-COVID-19 mRNA Vaccine (nucleoside-modified) (europa.eu) (Accessed on September 02, 2021).
[4] European Medicines Agency (EMA) website. Comirnaty. Overview. What measures are being taken to ensure the safe and effective use of Comirnaty? Available from: https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty#product-information-section (Accessed on September 02, 2021).
[5] Centers for Disease Control and Prevention. Myths and Facts about COVID-19 Vaccines. Last Updated August 27, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html (Accessed on September 02, 2021)."