

28-December-2020

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

Dear Ms [REDACTED]

Thank you for your enquiry regarding our medicine Comirnaty ▼.

**▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 of the Patient Information Leaflet for how to report side effects.**

**If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system and include batch/Lot number if available.<sup>1</sup>**

**This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine. The European Medicines Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.<sup>1</sup>**

The active substance is COVID-19 mRNA Vaccine.<sup>1</sup>

Like all vaccines, Comirnaty can cause side effects, although not everybody gets them.

**Very common side effects:** may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness
- headache
- muscle pain
- joint pain
- chills, fever

**Common side effects:** may affect up to 1 in 10 people

- injection site redness
- nausea

**Uncommon side effects:** may affect up to 1 in 100 people

- enlarged lymph nodes
- feeling unwell
- pain in limb
- insomnia
- injection site itching

**Rare side effects:** may affect up to 1 in 1,000 people

- temporary one sided facial drooping

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<sup>1</sup> Comirnaty (COVID-19 mRNA Vaccine). Patient Information Leaflet (centralized license), applicable to all countries in the EU and NO [V: Date of revision of text 12/2020;LC].

**Not known** (cannot be estimated from the available data)

- severe allergic reaction<sup>1</sup>

The active substance is COVID-19 mRNA Vaccine. After dilution, the vial contains 5 doses of 0.3 mL with 30 micrograms mRNA each.

The other ingredients are:

- ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
- 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
- 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
- cholesterol
- potassium chloride
- potassium dihydrogen phosphate
- sodium chloride
- disodium phosphate dihydrate
- sucrose
- water for injections<sup>1</sup>

### **Learn More:**

#### **What can I do with this information?**

This document provides an answer to your question about a Pfizer product, but it does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. This information is provided for informational purposes only and is not meant to be a substitute for advice provided by a doctor or other qualified health care professional. Patients should not use this information for diagnosing a health or fitness problem or disease. You should always talk with a doctor or other healthcare professional about whether a specific treatment or medication is right for you and before starting a new treatment or activity. They are in the best position to advise you about the suitability of a particular treatment as they have access to the details of your medical history, as well as to information on all medical products.

#### **Where can I get more information?**

Please refer to the full Patient Information Leaflet for COMIRNATY.

#### **What should I do if I get any side effects?**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the full Patient Information Leaflet for COMIRNATY. You can also report side effects directly via your national reporting system and include batch/Lot number if available.

Due to pharmaceutical regulations, we are unfortunately unable to provide you with information on this medicine, beyond that contained in the patient information leaflet.

For all further information regarding COMIRNATY, please consult your doctor, who is in the best position to advise you about the suitability of a particular treatment as he/she has access to the details of your medical history, as well as to information on all medical products.

However, should your physician wish to obtain further information on COMIRNATY from us, we shall be pleased to assist at any time.

Yours sincerely

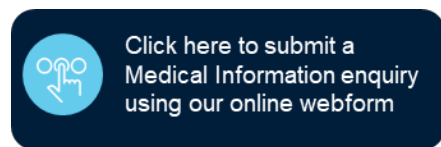


[REDACTED]  
Medical Information Officer

Ref: 00046071

To help us serve you better in the future, please take a few minutes to complete our survey which is found on the following link:

[https://pfizermi.qualtrics.com/SE/?SID=SV\\_7TLsDr25NMfzRnT&Q\\_lang=EN&CaseID=00046071&Product=COMIRNATY](https://pfizermi.qualtrics.com/SE/?SID=SV_7TLsDr25NMfzRnT&Q_lang=EN&CaseID=00046071&Product=COMIRNATY)



### Disclaimers

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