PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

COMIRNATY® Original & Omicron (BA.4/BA.5)

COVID-19 mRNA Vaccine, Bivalent (Original and Omicron BA.4/BA.5), Suspension for Intramuscular Injection

This leaflet is a summary and will not tell you everything about this vaccine. Talk to your/your child's healthcare professional about your/your child's medical condition and treatment and ask if there is any new information about **COMIRNATY Original & Omicron BA.4/BA.5**.

What is COMIRNATY Original & Omicron BA.4/BA.5 used for?

COMIRNATY Original & Omicron BA.4/BA.5 is a vaccine used to provide protection against COVID-19 disease caused by the SARS-CoV-2 virus.

COMIRNATY Original & Omicron BA.4/BA.5 can be given to people 5 years of age and older as a booster dose only.

The safety and effectiveness of a booster dose of COMIRNATY Original & Omicron BA.4/BA.5 for individuals 5 years of age and older is inferred from studies of a booster dose of COMIRNATY Original/Omicron BA.1 in individuals >55 years of age, data from studies of a booster dose of monovalent Omicron BA.1 in individuals 18 to ≤55 years of age as well as data from studies which evaluated the primary series and booster vaccination with COMIRNATY.

How does COMIRNATY Original & Omicron BA.4/BA.5 work?

The vaccine causes our body to produce protection (such as antibodies) that prevent the COVID-19 virus from entering our cells to make us sick. The vaccine uses a new method (messenger RNA - mRNA, the genetic code for a piece of the virus) to help our bodies make protection against the virus. The vaccine is given by injection with a needle in the upper arm.

You cannot get COVID-19 from the vaccine.

As with any vaccine, COMIRNATY Original & Omicron BA.4/BA.5 may not fully protect all those who receive it. Even after you/your child have had the vaccine, continue to follow the recommendations of local public health officials to prevent spread of COVID-19.

What are the ingredients in COMIRNATY Original & Omicron BA.4/BA.5?

Medicinal ingredient: mRNA (tozinameran and famtozinameran)

Non-medicinal ingredients:

- ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- cholesterol
- sodium chloride*
- sucrose
- tromethamine

- tromethamine hydrochloride
- water for injection

*not present in COMIRNATY Original & Omicron BA.4/BA.5 for 12 years of age and older

COMIRNATY Original & Omicron BA.4/BA.5 comes in the following dosage forms:

For 12 Years of Age and Older:

Vial with Gray Cap and Gray Label Border (DO NOT DILUTE): White to off-white suspension provided in a multiple dose vial of 6 doses of 0.3 mL, with 30 micrograms mRNA (15 mcg Original and 15 mcg Omicron BA.4/BA.5) each.

For Age 5 Years to <12 Years:

Vial with Orange Cap and Orange Label Border (DILUTE PRIOR TO USE): White to off-white suspension (to be diluted) provided in a multiple dose vial of 10 doses. After dilution, the vial contains 10 doses of 0.2 mL, with 10 micrograms mRNA (5 mcg Original and 5 mcg Omicron BA.4/BA.5) each.

You/your child should not receive COMIRNATY Original & Omicron BA.4/BA.5 if:

- you/your child are allergic to any of the ingredients in this vaccine (see **What are the ingredients in COMIRNATY Original & Omicron BA.4/BA.5?**).
- you/your child had a severe allergic reaction after a previous dose of COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original & Omicron BA.4/BA.5.
- you/your child have any symptoms that could be due to COVID-19. Talk with your/your child's healthcare professional about your/your child's symptoms and getting a COVID-19 test. Your/your child's healthcare professional will advise you when you/your child are able to receive the vaccine.

To help avoid side effects and ensure proper use, talk to your/your child's healthcare professional before you/your child receive COMIRNATY Original & Omicron BA.4/BA.5. Talk about any health conditions or problems you/your child may have, including if you/your child:

- have had any problems following a previous dose of COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original & Omicron BA.4/BA.5 such as an allergic reaction or breathing problems
- have any allergies
- have a weakened immune system due to a medical condition or are on a medicine that affects the immune system
- have previously had episodes of myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the outer lining of the heart)
- are feeling nervous about the vaccination process or have ever fainted in association with an injection
- have a bleeding problem, bruise easily or use a blood thinning medication
- are pregnant, think you may be pregnant or plan to become pregnant
- are breast-feeding

Other warnings you should know about:

As with any vaccine, COMIRNATY Original & Omicron BA.4/BA.5 may not fully protect all those who receive it.

Some of the effects of vaccination mentioned under "***What are possible side effects from using COMIRNATY Original* & *Omicron BA.4/BA.5?"*** may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

Tell your/your child's healthcare professional about all the medicines you/your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

There is no information on the use of COMIRNATY Original & Omicron BA.4/BA.5 with other vaccines.

Tell your healthcare professional if you/your child have recently received any other vaccine.

How COMIRNATY Original & Omicron BA.4/BA.5 is given:

Usual dose:

For 12 Years of Age and Older

COMIRNATY Original & Omicron BA.4/BA.5 is given as an injection of 0.3 mL, preferably into a muscle of the upper arm.

A booster dose of COMIRNATY Original & Omicron BA.4/BA.5 may be administered intramuscularly at least 3 to 6 months after completing the primary course of COMIRNATY and/or a previous booster dose of COMIRNATY in individuals 12 years of age or older.

For Age 5 Years to <12 Years

COMIRNATY Original & Omicron BA.4/BA.5 is given as an injection of 0.2 mL, preferably into a muscle of the upper arm.

A booster dose of COMIRNATY Original & Omicron BA.4/BA.5 may be administered intramuscularly at least 6 months after completing the primary course of COMIRNATY in children 5 years to <12 years.

If you have any further questions on the use of COMIRNATY Original & Omicron BA.4/BA.5, ask your healthcare professional.

Overdose:

In the event of suspected overdose with COMIRNATY Original & Omicron BA.4/BA.5, contact your regional poison control centre.

Missed Dose:

If you forget to go back to your healthcare professional at the scheduled time for your/your child's next dose, ask your/your child's healthcare professional for advice.

What are possible side effects from using COMIRNATY Original & Omicron BA.4/BA.5?

Like all vaccines, COMIRNATY Original & Omicron BA.4/BA.5 can cause side effects, although not everybody gets them.

Side effects may occur at the following frequencies:

Very common: may affect more than 1 in 10 people

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

Common: may affect more than 1 in 100 and up to 1 in 10 people

- injection site redness
- nausea
- vomiting

Uncommon: may affect more than 1 in 1000 and up to 1 in 100 people

- enlarged lymph nodes
- feeling unwell
- arm pain
- feeling weak or lack of energy/sleepy
- decreased appetite
- excessive sweating
- night sweats

Non-severe allergic reactions (such as rash, itching, hives or swelling of the face), severe allergic reactions, facial paralysis / Bell's palsy, erythema multiforme (skin reaction or lesion; red spots or patches), hypoesthesia (reduced or loss of sensation) and paresthesia ("tingling sensation") have been reported. Myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the outer lining of the heart) have been reported following COMIRNATY administration.

These are not all the possible side effects you/your child may have when taking COMIRNATY Original & Omicron BA.4/BA.5. If you/your child experience any side effects not listed here, tell your/your child's healthcare professional.

There is a remote chance that COMIRNATY Original & Omicron BA.4/BA.5 could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of COMIRNATY Original & Omicron BA.4/BA.5. For this reason, the vaccination provider may ask you/your child to stay at the place where the vaccine was received for monitoring after vaccination. Should you/your child develop any serious symptoms or symptoms that could be an allergic reaction, seek medical attention right away. Symptoms of an allergic reaction include:

- hives (bumps on the skin that are often very itchy)
- swelling of the face, tongue or throat
- difficulty breathing
- a fast heartbeat
- dizziness and weakness

If you/your child experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Your/your child's health care provider should inform your local public health department of any serious side effects after vaccination.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Pfizer Canada ULC cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html) and send it to your local Health Unit.

Storage:

COMIRNATY Original & Omicron BA.4/BA.5 should be stored, supplied and administered by a healthcare professional.

Keep out of reach and sight of children.

If you want more information about COMIRNATY Original & Omicron BA.4/BA.5**:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website [www.pfizer.ca], or by calling 1-800-463-6001 (Pfizer Medical Information).

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