PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

COMIRNATY® Omicron (XBB.1.5)

COVID-19 mRNA Vaccine, Monovalent (Omicron XBB.1.5), 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 Omicron XBB.1.5**.

What is COMIRNATY Omicron XBB.1.5 used for?

COMIRNATY Omicron XBB.1.5 is a vaccine used to provide protection against COVID-19 disease caused by the SARS-CoV-2 virus.

COMIRNATY Omicron XBB.1.5 can be given to people 6 months of age and older.

The safety and effectiveness of COMIRNATY Omicron XBB.1.5 for individuals 6 months of age and older are based on studies which evaluated the primary series and booster vaccination with COMIRNATY and supported by studies which evaluated a booster dose of COMIRNATY Original & Omicron BA.4/BA.5 in individuals 6 months of age and older. Data obtained with COMIRNATY and COMIRNATY Original & Omicron BA.4/BA.5 are relevant to COMIRATY Omicron XBB.1.5 because these vaccines are manufactured using the same process.

How does COMIRNATY Omicron XBB.1.5 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 Omicron XBB.1.5 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 Omicron XBB.1.5?

Medicinal ingredient: mRNA (raxtozinameran)

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
- cholesterol
- DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine
- sodium chloride*
- sucrose
- tromethamine
- tromethamine hydrochloride
- water for injection

*not present in COMIRNATY Omicron XBB.1.5 for 12 years of age and older (gray cap and gray label border) and for 5 Years to <12 years of age (blue cap and blue label border)

COMIRNATY Omicron XBB.1.5 comes in the following dosage forms:

For 12 Years of Age and Older:

Single Dose Vial with Gray Cap and Gray Label Border (DO NOT DILUTE): White to off-white suspension provided in a single dose vial of 1 dose of 0.3 mL, with 30 micrograms mRNA (30 mcg Omicron XBB.1.5) each.

Multiple Dose 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 (30 mcg Omicron XBB.1.5) each.

For Age 5 Years to <12 Years:

Multiple Dose 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 multiple dose vial contains 10 doses of 0.2 mL, with 10 micrograms mRNA (10 mcg Omicron XBB.1.5) each.

Single Dose Vial with Blue Cap and Blue Label Border (DO NOT DILUTE): White to off-white suspension provided in a single dose vial of 1 dose of 0.3 mL, with 10 micrograms mRNA (10 mcg Omicron XBB.1.5) each.

Multiple Dose Vial with Blue Cap and Blue Label Border (DO NOT DILUTE): White to off-white suspension provided in a multiple dose vial of 6 doses of 0.3 mL, with 10 micrograms mRNA (10 mcg Omicron XBB.1.5) each.

For Age 6 Months to <5 Years:

Multiple Dose Vial with Maroon Cap and Maroon 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 3 micrograms mRNA (3 mcg Omicron XBB.1.5) each.

You/your child should not receive COMIRNATY Omicron XBB.1.5 if:

- you/your child are allergic to any of the ingredients in this vaccine (see **What are the ingredients in COMIRNATY Omicron XBB.1.5?**).
- 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 Omicron XBB.1.5. 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 Omicron XBB.1.5 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 Omicron XBB.1.5?"*** 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 Omicron XBB.1.5 with other vaccines.

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

How COMIRNATY Omicron XBB.1.5 is given:

Usual dose:

For 12 Years of Age and Older

COMIRNATY Omicron XBB.1.5 is given as an injection of 0.3 mL, preferably into a muscle of the upper arm.

You will receive 1 injection, regardless whether you have received a COVID-19 vaccine before.

If you were previously vaccinated with a COVID-19 vaccine, you should not receive a dose of COMIRNATY Omicron XBB.1.5 until at least 3 to 6 months after the most recent dose.

For Age 5 Years to <12 Years

DILUTE PRIOR TO USE (Multiple Dose Vial with Orange Cap and Orange Label Border)

COMIRNATY Omicron XBB.1.5 is given as an injection of 0.2 mL, preferably into a muscle of the upper arm.

DO NOT DILUTE (Single Dose or Multiple Dose Vials with Blue Cap and Blue Label Border)

COMIRNATY Omicron XBB.1.5 is given as an injection of 0.3 mL, preferably into a muscle of the upper arm.

Your child will receive 1 injection, regardless whether he/she has received a COVID-19 vaccine before.

If your child was previously vaccinated with a COVID-19 vaccine, he/she should not receive a dose of COMIRNATY Omicron XBB.1.5 until at least 6 months after the most recent dose.

For Age 6 Months to <5 Years

COMIRNATY Omicron XBB.1.5 is given as an injection of 0.2 mL, into a muscle of the thigh in infants from 6 to less than 12 months of age. In infants and children 1 year of age or older, it is given as an injection of 0.2 mL into a muscle of the thigh or into a muscle of the upper arm.

If your child has not completed a COVID-19 primary vaccination course, your child will receive a maximum of 3 injections (the total number of doses required as primary course). It is recommended to receive the second dose 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose to complete the three-dose course. If your child has started a three-dose course with COMIRNATY or COMIRNATY Original & Omicron BA.4/BA.5, they may complete the three-dose course with COMIRNATY Omicron XBB.1.5.

If your child has previously completed a COVID-19 primary vaccination course, your child will receive 1 injection. If your child was previously vaccinated with a COVID-19 vaccine, your child should not receive a dose of COMIRNATY Omicron XBB.1.5 until at least 6 months after the most recent dose.

If you have any further questions on the use of COMIRNATY Omicron XBB.1.5, ask your healthcare professional.

Overdose:

In the event of suspected overdose with COMIRNATY Omicron XBB.1.5, 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 Omicron XBB.1.5?

Like all vaccines, COMIRNATY Omicron XBB.1.5 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

- irritability (6 months to <2 years)
- injection site pain/tenderness, 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 ("very common" in 6 months to <12 years)
- nausea

- vomiting
- rash (6 months to <2 years)
- enlarged lymph nodes (more frequently observed after the booster dose)

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

- feeling unwell
- arm pain
- feeling weak or lack of energy/sleepy
- decreased appetite ("very common" for 6 months to <2 years)
- 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 receiving COMIRNATY Omicron XBB.1.5. 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 Omicron XBB.1.5 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 Omicron XBB.1.5. 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 Omicron XBB.1.5 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 Omicron XBB.1.5**:**

- 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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