PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

COMIRNATY®

COVID-19 Vaccine, mRNA, 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**.

What is COMIRNATY used for?

COMIRNATY is a vaccine used to prevent COVID-19 disease caused by the SARS-CoV-2 virus.

COMIRNATY can be given to people from 6 months of age and older.

How does COMIRNATY 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 intramuscular injection with a needle.

You cannot get COVID-19 from the vaccine.

As with any vaccine, COMIRNATY 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?

Medicinal ingredient: mRNA

Non-medicinal ingredients: The non-medicinal ingredients differ depending on which version of the vaccine is given. If you are uncertain, check with your vaccination provider.

For 12 Years of Age or Older: DILUTE BEFORE USE (Vial with Purple Cap and Purple Label Border):

- 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
- dibasic sodium phosphate dihydrate
- monobasic potassium phosphate
- potassium chloride
- sodium chloride
- sucrose
- water for injection

For 12 Years of Age and Older: DO NOT DILUTE (Vial with Gray Cap and Gray Label Border) ***and***

For Age 5 Years to <12 Years: DILUTE PRIOR TO USE (Vial with Orange Cap and Orange Label Border) ***and***

For Age 6 Months to <5 Years: DILUTE PRIOR TO USE (Vial with Maroon Cap and Maroon Label Border)

- 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 for 12 years of age and older: DO NOT DILUTE (Vial with Gray Cap and Label Border)

COMIRNATY comes in the following dosage forms:

For 12 Years of Age and Older:

There are two COMIRNATY presentations available for use in individuals 12 years of age and older:

Vial with Purple Cap and Purple Label Border (DILUTE BEFORE USE): White to off-white suspension (to be diluted) provided in a multiple dose vial of 6 doses. After dilution, the vial contains 6 doses of 0.3 mL, with 30 micrograms mRNA each.

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 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 each.

For Age 6 Months to <5 Years:

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 each.

You/your child should not receive COMIRNATY if:

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

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

How COMIRNATY is given:

Usual dose:

<u>For 12 Years of Age and Older:</u>

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

You/your child will receive 2 injections, given 3 weeks apart. It is very important to return for the second injection, or the vaccine may not work as well.

A booster dose of COMIRNATY may be given at least 6 months after completion of the primary series in individuals 16 years of age and older.

<u>For Age 5 Years to <12 Years:</u>

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

Your child will receive 2 injections, given 3 weeks apart. It is very important that they return for the second injection, or the vaccine may not work as well.

A booster dose of COMIRNATY may be given at least 6 months after completion of a primary series in individuals 5 years through <12years of age.

For Age 6 Months to <5 Years:

COMIRNATY 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, COMIRNATY is given as an injection of 0.2 mL into a muscle of the thigh or into a muscle of the upper arm.

Your child will receive 3 injections.

It is recommended to receive the second dose of the same vaccine 3 weeks after the first dose, followed by a third dose at least 8 weeks after the second dose to complete the vaccination series.

If your child will turn from 4 to 5 years of age between their doses in the vaccination series, they should receive their age-appropriate dose at the time of the vaccination. The interval between doses is determined by your child's age at the start of the vaccination series.

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

Overdose:

In the event of suspected overdose with COMIRNATY, 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?

Like all vaccines, COMIRNATY 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)

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 ("very common" for 6 months to <2 years)
- excessive sweating
- night sweats
- dizziness

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. 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 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. 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 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**:**

- 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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