

COMIRNATY[®]

(COVID-19 Vaccine, mRNA)

**YOUR QUESTIONS ANSWERED
ABOUT COMIRNATY AND
COMIRNATY ORIGINAL
& OMICRON BA.4/BA.5
BIVALENT VACCINE**
(the Pfizer-BioNTech COVID-19 vaccines)



COMIRNATY is used for the prevention of COVID-19 disease caused by the SARS-CoV-2 virus in individuals 6 months of age and older; COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine is used to provide protection against COVID-19 disease caused by the SARS-CoV-2 virus in individuals 5 years of age and older.



BIONTECH

COMIRNATY

COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine

This brochure provides important information to help you understand the benefits, risks, and how COMIRNATY works. This vaccine has been offered or given to you/your child in response to the ongoing COVID-19 pandemic. COMIRNATY may not protect everyone. Talk to your/your child's vaccination provider if you have questions concerning COMIRNATY.

What is COMIRNATY used for?

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

The vaccine can be given to people who are 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, or mRNA, which acts as a blueprint for a piece of the virus) to help our bodies make protection against the virus.

So, instead of using the live virus, mRNA vaccines teach our cells how to make a protein (i.e., a piece of the virus) that will trigger an immune response. Once triggered, our body then makes antibodies (protection). These antibodies help us fight infection if the real virus does enter our body in the future.

You and your child cannot get COVID-19 from the vaccine.

As with any vaccine, COMIRNATY may not fully protect all those who receive it.

It is important to remember that even after you/your child have had the vaccine, you/your child should continue to follow the recommendations of local public health officials to help prevent the spread of COVID-19.

Who should not receive COMIRNATY?

You/your child should not receive the vaccine if 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
- had a severe allergic reaction after a previous dose of COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original & Omicron BA.4/BA.5
- are allergic to any of the ingredients in this vaccine

It is important to remember to tell the vaccination provider about any severe allergies you/your child have, including food/medication/other allergies, before getting vaccinated.

How is COMIRNATY given?

Usual dose:

5 years of age and older

COMIRNATY is injected into a muscle of your/your child's **upper arm** (as an injection of 0.3 mL for those 12 years of age and older, or 0.2 mL for those 5 to <12 years).

You/your child (≥5 years) will receive **2 injections**, given **3 weeks apart**.



First
injection



3
weeks



Second
injection

6 months to <5 years old

COMIRNATY is injected into a muscle of the **thigh** in children 6 months to <12 months of age, and into a muscle of the **upper arm or thigh** in children ≥1 year to <5 years (as an injection of 0.2 mL).

Your child (6 months to <5 years) will receive **3 injections**. The second dose should be given **3 weeks after the first**, followed by a third dose **at least 8 weeks after the second**.



First
injection



3
weeks



Second
injection



8
weeks



Third
injection

It is very important that you/your child return for all doses, or the vaccine may not work as well.

It may take up to 7 days **after the last dose** of COMIRNATY to develop protection against COVID-19.

If you have any further questions on the use of COMIRNATY, ask your/your child's vaccination provider.

What do I do if I miss my or my child's subsequent dose?

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

Who may receive a booster dose of COMIRNATY?

People 16 years of age and older may be given a booster dose of COMIRNATY (original vaccine) at least 6 months after the second dose. Children 5 years through <12 years of age may also be given a booster dose of COMIRNATY at least 6 months after the second dose.

COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine can also be given as a booster in individuals 5 years and older. Ask your healthcare provider which vaccine option is suitable for you. For information on booster doses with the bivalent vaccine in individuals 5 years of age and older, refer to the **COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine booster section**.



Ask for COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine when you return for your booster dose

What should I let my vaccination provider know before getting COMIRNATY?

To help avoid side effects, you should 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

Tell your/your child's vaccination provider about all 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/your child's vaccination provider if you/your child have recently received any other vaccine.

What are possible side effects from COMIRNATY?

Like all vaccines, COMIRNATY can cause side effects.

Side effects may occur at the following frequencies:

- Very common (may affect more than 1 in 10 people): injection-site pain/tenderness, injection-site swelling, tiredness, headache, muscle pain, chills, joint pain, fever, diarrhea and irritability (in children aged 6 months to <2 years)
- Common (may affect more than 1 in 100 and up to 1 in 10 people): injection-site redness (“very common” in children aged 6 months to <12 years), nausea, vomiting, and rash (in children aged 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” in children aged 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 experience when receiving COMIRNATY. If you/your child experience a side effect listed here or not, you should talk to your/your child’s vaccination provider.

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, your/your child’s 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)
- difficulty breathing
- swelling of the face, tongue or throat
- a fast heartbeat
- dizziness and weakness

If you/your child experience a severe allergic reaction, seek immediate medical attention by calling 9-1-1, or going to the nearest hospital.

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

The vaccine is used to provide protection against COVID-19 disease caused by the SARS-CoV-2 virus.

COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine can be given to people 5 years of age and older.

The safety and effectiveness of a primary course or booster dose of COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine for individuals 5 years of age and older is inferred from studies which evaluated the primary series and booster vaccination with COMIRNATY in individuals >5 years of age, and supported by studies of a booster dose of COMIRNATY Original & Omicron BA.4/BA.5 in individuals >5 years of age.

Marketing authorization has been issued with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and effectiveness of the vaccine.

You and your child cannot get COVID-19 from the vaccine.

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

It is important to remember that even after you/your child have had the vaccine, you/your child should continue to follow the recommendations of local public health officials to help prevent the spread of COVID-19.

Who should not receive COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine?

You/your child should not receive the vaccine if 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
- had a severe allergic reaction after a previous dose of COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original & Omicron BA.4/BA.5
- are allergic to any of the ingredients in this vaccine

How is COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine given?

Usual dose:

12 years of age and older

COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine is injected into a muscle of your/your child's **upper arm** (as an injection of 0.3 mL for those **12 years of age and older**).

A **primary vaccination course** of COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine may be administered as a series of **2 injections**, given **3 weeks apart**. It is very important to return for the second injection, or the vaccine may not work as well.



First injection



3 weeks



Second injection

5 to <12 years

COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine is injected into a muscle of your child's **upper arm** (as an injection of 0.2 mL for those **5 to <12 years**).

A **primary vaccination course** of COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine may be administered as a series of **2 injections**, given **3 weeks apart**. It is very important to return for the second injection, or the vaccine may not work as well.



First injection



3 weeks



Second injection

A **booster dose** of COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine 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.



BOOSTER DOSE:
3–6 months after the
PRIMARY (2-dose) course
of COMIRNATY

OR



BOOSTER DOSE:
3–6 months after a
PREVIOUS BOOSTER dose
of COMIRNATY

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



BOOSTER DOSE:
6 months after the PRIMARY (2-dose) course or a
PREVIOUS BOOSTER dose of COMIRNATY

If you have any further questions on the use of COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine, ask your/your child's vaccination provider.

What do I do if I miss my or my child's booster dose?

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

What should I let my vaccination provider know before getting COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine?

To help avoid side effects, before you receive the vaccine, you should 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

Tell your/your child's vaccination provider about all 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 bivalent vaccine with other vaccines. Tell your/your child's vaccination provider if you/your child have recently received any other vaccine.

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

Like all vaccines, COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine can cause side effects.

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, 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, 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 experience when receiving COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine. If you/your child experience a side effect listed here or not, you should talk to your/your child's vaccination provider.

There is a remote chance that COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine 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 bivalent vaccine. For this reason, your/your child's 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, seek immediate medical attention by calling 9-1-1, or going to the nearest hospital.

Reporting a Side Effect

Should you/your child experience a side effect following immunization, please report it to your/your child's healthcare professional. Should you/your child require information related to the management of the side effect, please contact your/your child's healthcare professional.

We also encourage you to visit our designated safety web portal, where you can efficiently and seamlessly report your experience with COMIRNATY or COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine. You can access this web portal at www.pfizersafetyreporting.com.

Stay up to date on the latest information on COVID-19

Take a look at the following useful links:

- Health Canada at www.canada.ca/en/health-canada.html
- Public Health Agency of Canada at www.canada.ca/en/public-health/
- Immunize Canada at www.immunize.ca

COMIRNATY

helping deliver COVID-19
vaccination in communities from
**COAST TO COAST
TO COAST.**

**60+ million
doses in Canada**

including over
3 million doses
given to children
aged 5 to 11.

**2.5+ billion
doses worldwide**

and those
numbers continue
to increase.



When it's time for your next dose,
ask your healthcare provider
about COMIRNATY and
COMIRNATY Original & Omicron
BA.4/BA.5 bivalent vaccine.

 **COMIRNATY**[®]
(COVID-19 Vaccine, mRNA)

 **Pfizer**

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