COVID-19 Vaccine (Adenovirus Vector)

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Pronunciation

(KO vid nine teen vak SEEN ad e noh VYE rus vek tor)

Brand Names: US

Janssen COVID-19 Vaccine

Brand Names: Canada

AstraZeneca COVID-19 Vaccine [DSC]; Covishield [DSC]; Jcovden; Vaxzevria

Warning

- Very rarely, blood clots with low blood platelet levels (thrombosis with thrombocytopenia syndrome or TTS) have happened in people who got this vaccine. This has happened most often in females between 30 and 49 years old. Most of the time, signs started within 2 weeks after the vaccine. Sometimes this has been deadly. These blood clots happened in different places, including the brain, stomach area, and legs. Call your doctor right away if you have any of these signs: Easy bruising or tiny blood spots away from the injection site, severe headache, headache that does not go away, stomach pain that does not go away, leg swelling or pain, chest pain, shortness of breath, blurred eyesight, seizures, or feeling confused.

What is this drug used for?

- It is used to prevent COVID-19.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug (including polysorbate 80); or any other drugs, foods, or substances (including polyethylene glycol). Tell your doctor about the allergy and what signs you had.

- If you have COVID-19, if you have any symptoms that could be from COVID-19, if you are waiting to find out COVID-19 test results, or if you recently had COVID-19.

- If you have an illness with a fever.

- If you have bleeding problems.
• If you have ever had a health problem with blood clots and low blood platelet levels (thrombosis with thrombocytopenia syndrome or TTS). This includes heparin-induced thrombocytopenia (HIT).

• If you have had a nerve problem called Guillain-Barre syndrome within 6 weeks after getting this vaccine.

• If you have ever had a health problem called capillary leak syndrome.

• If you have ever had certain heart problems (myocarditis, pericarditis).

• If you have ever had a health problem called multisystem inflammatory syndrome (MIS).

• If you are taking aspirin or a blood thinner.

• If you have ever had a different COVID-19 vaccine.

• If you have been exposed to someone who has COVID-19 within the past 14 days.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

• Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.

• This vaccine cannot cause COVID-19.

• Some products are given as 1 dose, while others need to be given as 2 doses. Some people may also be able to get booster doses (may be a different Covid-19 vaccine). Talk with your doctor or pharmacist if you have questions.

• It is not known how long people who get this vaccine will be protected from COVID-19.

• Like all vaccines, this vaccine may not fully protect all people who get it. If you have questions, talk with the doctor.

• If you have side effects after a dose, acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen or naproxen may help.

• After getting the vaccine, continue to do things that prevent the spread of COVID-19 as recommended by local public health officials. These include washing hands often, wearing a mask, staying at least 6 feet away from other people, and avoiding crowds.

• If you have a weak immune system or take drugs that weaken the immune system, talk with your doctor. This vaccine may not work as well. Some people may need to get a COVID-19 vaccine again.
• People who got this vaccine before or during a stem cell transplant or chimeric antigen receptor [CAR]-T therapy may need to get a COVID-19 vaccine again. If you have had or are having one of these treatments, talk with your doctor.

• This vaccine may affect syphilis test results. Tell all your health care providers and lab workers if you have gotten this vaccine in the past 5 months.

• Rarely, cases of Bell's palsy happened with some of these vaccines. This usually goes away after some time. It is not known if the vaccine may be the cause. Tell your doctor if you have ever had Bell's palsy. Call your doctor right away if you have signs like weak or drooping muscles on one side of your face.

• Very rarely, nerve problems like Guillain-Barre syndrome (GBS) have happened in people who got this vaccine. Most of the time symptoms of GBS started within 42 days after the vaccine. The highest risk was seen in people between 40 and 64 years of age. Most of the time, GBS happened in males. Talk with your doctor if you have questions.

• Rarely, this drug has caused a severe and sometimes deadly problem called capillary leak syndrome (CLS). CLS may lead to low blood pressure, abnormal heartbeat, chest pain, or heart attack. It may also lead to lung or breathing problems, bleeding or lower blood flow in the stomach or bowel, kidney problems, swelling, or feeling confused. If you have questions, talk with the doctor.

• Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

What are some side effects that I need to call my doctor about right away?

• WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

• Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

• Signs of nerve problems like weakness, numbness, tingling, trouble walking, trouble with face movements (like speaking, chewing, or swallowing), seeing double, not able to move your eyes, or trouble with bladder or bowel control.

• Fast heartbeat, dizziness, passing out, weakness, swelling in the arms or legs, or sudden weight gain. These may be other signs of an allergic reaction or other type of reaction.

• A burning, numbness, or tingling feeling that is not normal.

• Small red or purple, flat round spots under the skin.

• Ringing in ears.
• Rarely, a type of low blood platelet levels called immune thrombocytopenia (ITP) has happened in people who got this vaccine. Most of the time, this happened within 42 days after the vaccine. If you have ever had ITP, talk with your doctor. Call your doctor right away if you have any unexplained bruising or bleeding.

• Some heart problems have very rarely happened with this vaccine. Most of the time, signs started within 8 days after getting this vaccine. Call your doctor right away if you have chest pain; shortness of breath; or feel like your heart is beating fast, fluttering, or pounding. If you have questions or concerns about this information, talk with the doctor.

What are some other side effects of this drug?

• All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

• Pain, redness, or swelling where the injection was given; headache; muscle or joint pain; fever of 100.4°F (38°C) or higher; chills; upset stomach, throwing up, or diarrhea; swollen or tender glands; or feeling tired or unwell. Most side effects have been mild. Most of the time these went away within 1 to 2 days after the injection.

• These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

• You may report side effects to your national health agency.

• Report side effects to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html or by calling 1-800-822-7967. There is also a smartphone tool called V-safe that may be used to check how you are doing and to report side effects. This can be found at https://vsafe.cdc.gov. If you need help with V-safe, call 1-800-232-4636.

How is this drug best taken?

• Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

• It is given as a shot into a muscle.

• You will be watched closely while you receive this drug and for some time after your dose. Talk with your doctor.

What do I do if I miss a dose?

• Call your doctor to find out what to do. For the most protection against COVID-19, it is important that you do not miss or skip doses.

How do I store and/or throw out this drug?

• This injection will be given to you in a healthcare setting. You will not store it at home.
General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Last Reviewed Date

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