Package leaflet: Information for the user

Nuvaxovid dispersion for injection
COVID-19 Vaccine (recombinant, adjuvanted)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nuvaxovid is and what it is used for
2. What you need to know before you receive Nuvaxovid
3. How Nuvaxovid is given
4. Possible side effects
5. How to store Nuvaxovid
6. Contents of the pack and other information

1. What Nuvaxovid is and what it is used for

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

Nuvaxovid is given to individuals 12 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and specialised white blood cells that work against the virus, to give protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

2. What you need to know before you receive Nuvaxovid

Nuvaxovid should not be given
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist, or nurse before you are given Nuvaxovid if:
- you have ever had a severe or life-threatening allergic reaction after receiving any other vaccine injection or after you were given Nuvaxovid in the past,
- you have ever fainted following any needle injection,
- you have a high fever (over 38°C) or severe infection. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold,
- you have bleeding problems, you bruise easily, or you use a medicine to prevent blood clots,
- your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants, or cancer medicines).

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Nuvaxovid (see section 4).

These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days.
Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist, or nurse before you are given Nuvaxovid.

As with any vaccine, the 2-dose vaccination course of Nuvaxovid may not fully protect all those who receive it, and it is not known how long you will be protected.

Children

Nuvaxovid is not recommended for children aged below 12 years. Currently, there is no information available on the use of Nuvaxovid in children younger than 12 years of age.

Other medicines and Nuvaxovid

Tell your doctor, pharmacist, or nurse if you are taking, have recently taken, or might take any other medicines or vaccines.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist, or nurse for advice before you receive this vaccine.

Driving and using machines

Some of the side effects of Nuvaxovid listed in section 4 (Possible side effects) may temporarily reduce your ability to drive and use machines (for example, feeling faint or lightheaded or feeling very tired).

Do not drive or use machines if you are feeling unwell after vaccination. Wait until any effects of the vaccine have worn off before you drive or use machines.

Nuvaxovid contains sodium and potassium

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

This vaccine contains less than 1 mmol potassium (39 milligrams) per dose, that is to say, essentially ‘potassium-free’.

3. How Nuvaxovid is given

Individuals 12 years of age and older
Nuvaxovid will be given to you as two separate 0.5 mL injections.

Your doctor, pharmacist, or nurse will inject the vaccine into a muscle, usually in your upper arm.

It is recommended that you receive the second dose of Nuvaxovid 3 weeks after your first dose to receive the full course of this vaccine.

A booster dose of Nuvaxovid may be given approximately 6 months after the second dose in individuals 18 years of age and older.

During and after each injection of the vaccine, your doctor, pharmacist, or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction.

If you miss an appointment for your second injection of Nuvaxovid, ask your doctor or nurse for advice. If you miss a scheduled injection, you may not be fully protected against COVID-19.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them. Most side effects go away within a few days of appearing. If symptoms persist, contact your doctor, pharmacist, or nurse.

As with other vaccines, you may feel pain or discomfort at the injection site, or you may see some redness and swelling at this site. However, these reactions usually clear up within a few days.

Get **urgent** medical attention if you get any of the following signs and symptoms of an allergic reaction:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat
- hives or rash
- nausea or vomiting
- stomach pain

Talk to your doctor or nurse if you develop any other side effects. These can include:

Very common (may affect more than 1 in 10 people):

- headache
- feeling sick (nausea) or getting sick (vomiting)
- muscle ache
- joint pain
- tenderness or pain where the injection is given
- feeling very tired (fatigue)
- generally feeling unwell

Common (may affect up to 1 in 10 people):

- redness where the injection is given
- swelling where the injection is given
- fever (>38°C)
- chills
- pain or discomfort in the arm, hand, leg and/or foot (pain in the extremity)

Uncommon (may affect up to 1 in 100 people):

- enlarged lymph nodes
- high blood pressure
- itchy skin, rash or hives
- redness of the skin
- itchy skin where the injection is given

Not known (cannot be estimated from available data):

- severe allergic reaction
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis), which can result in breathlessness, palpitations or chest pain.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Coronavirus Yellow Card reporting site https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store, and include the vaccine brand and batch/lot number, if available. By reporting side effects, you can help provide more information on the safety of this vaccine.

5. How to store Nuvaxovid

Keep this medicine out of the sight and reach of children.

Your doctor, pharmacist, or nurse is responsible for storing this vaccine and disposing of any unused product correctly.

Information about storage, expiry, use and handling are described in the section intended for healthcare professionals at the end of the package leaflet.

6. Contents of the pack and other information

What Nuvaxovid contains

- One dose (0.5 mL) Nuvaxovid contains 5 micrograms of SARS-CoV-2 spike protein* and is adjuvanted with Matrix-M.

  *produced by recombinant DNA technology using a baculovirus expression system in an insect cell line that is derived from Sf9 cells of the *Spodoptera frugiperda* species.

- Matrix-M is included in this vaccine as an adjuvant. Adjuvants are substances included in certain vaccines to accelerate, improve, and/or prolong the protective effects of the vaccine. Matrix-M adjuvant contains Fraction-A (42.5 micrograms) and Fraction-C (7.5 micrograms) of *Quillaja saponaria* Molina extract per 0.5 mL dose.

- The other ingredients (excipients) included in Nuvaxovid are:
  - Disodium hydrogen phosphate heptahydrate
  - Sodium dihydrogen phosphate monohydrate
  - Disodium hydrogen phosphate dihydrate
  - Sodium chloride
  - Polysorbate 80
  - Cholesterol
  - Phosphatidylcholine (including all-rac-α-Tocopherol)
  - Potassium dihydrogen phosphate
  - Potassium chloride
  - Sodium hydroxide (for the adjustment of pH)
  - Hydrochloric acid (for the adjustment of pH)
  - Water for Injections

What Nuvaxovid looks like and contents of the pack

- The dispersion is colourless to slightly yellow, clear to mildly opalescent (pH 7.2).

5-dose vial
- 2.5 mL of dispersion for injection in a vial with a rubber stopper and a blue flip-off top.
- Pack size: 10 multidose vials. Each vial contains 5 doses of 0.5 mL

10-dose vial
- 5 mL of dispersion in a vial with a rubber stopper and a blue flip-off top.
- Pack size: 10 multidose vials. Each vial contains 10 doses of 0.5 mL

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Novavax CZ a.s.
Bohumil 138
Jevany, 28163
Czechia

Manufacturer
Novavax CZ a.s.
Bohumil 138
Jevany, 28163
Czechia

This leaflet was last revised in June 2023 .

This vaccine has been given 'conditional approval'. This means that there is more evidence to come about this vaccine. New information on this vaccine will be reviewed at least every year and this leaflet will be updated as necessary.

Scan the code with a mobile device to access an electronic copy of the package leaflet for Great Britain.

Or visit the URL: https://www.NovavaxCovidVaccine.com

To listen to or request a copy of this leaflet in Braille, large print, or audio, please call 0800 198 5000 (free of charge).

Please be ready to give the following information when you call:
Product name: Nuvaxovid dispersion for injection
Reference number: PLGB 54180/0002

This is a service provided by the Royal National Institute of Blind people.

The following information is intended for healthcare professionals only:

Administer Nuvaxovid intramuscularly, preferably into the deltoid muscle of the upper arm, as two doses, 3 weeks apart.

A booster dose of Nuvaxovid may be given approximately 6 months after the second dose in individuals 18 years of age and older.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions and administration

Do not use this vaccine after the expiry date which is stated on the label and the carton after EXP. The expiry date refers to the last day of that month.

This vaccine should be handled by a healthcare professional using aseptic techniques to ensure the sterility of each dose.

Preparation for use

- The vaccine comes ready to use.
- Unopened vaccine should be stored in a refrigerator (2°C - 8°C) and kept within the outer carton to protect from light.
- Immediately prior to use, remove the vaccine vial from the carton in the refrigerator.
- Record the date and time of discard on the vial label. Use within 12 hours at 2°C to 8°C or 6 hours at room temperature (maximum 25°C) after first puncture.

Inspect the vial

- Gently swirl the multidose vial before and in between each dose withdrawal. Do not shake.
- Each multidose vial contains a colourless to slightly yellow, clear to mildly opalescent dispersion.
- Visually inspect the contents of the vial for visible particulate matter and/or discolouration prior to administration. Do not administer the vaccine if either are present.

Administer the vaccine

- An overfill is included per vial to ensure that a maximum of 5 doses (vial of 2.5 mL) or 10 doses (vial of 5 mL) of 0.5 mL each can be extracted.
- Each 0.5 mL dose is withdrawn into a sterile needle and sterile syringe to be administered by intramuscular injection, preferably in the deltoid muscle of the upper arm.
    - Do not mix the vaccine in the same syringe with any other vaccines or medicinal products.
    - Do not pool excess vaccine from multiple vials.

Storage after first needle puncture

- Store the opened vial between 2°C to 8°C for up to 12 hours or at room temperature (maximum 25°C) for up to 6 hours after first puncture.

Discard

- Discard this vaccine if not used within 12 hours when stored between 2°C to 8°C or 6 hours when stored at room temperature after first puncture of the vial, see section 6.3.

Disposal

- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.