

SPIKEVAX COVID-19 VACCINE

Elasomeran

Consumer Medicine Information

This vaccine has **provisional approval** in Australia to prevent COVID-19 disease caused by SARS-CoV-2 virus in individuals 18 years of age and older. This approval has been granted on the basis of short term efficacy and safety data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed.

This leaflet provides important information about using SPIKEVAX. **You should also speak to your doctor, pharmacist, or nurse if you would like further information or if you have any concerns or questions about using SPIKEVAX.**

Where to find information in this leaflet:

1. Why am I being given SPIKEVAX?
2. What should I know before I am given SPIKEVAX?
3. What if I am taking other medicines?
4. How will I be given SPIKEVAX?
5. What should I know about being given SPIKEVAX?
6. Are there any side effects?
7. Product details

1. Why am I being given SPIKEVAX?

SPIKEVAX contains the active ingredient Elasomeran.

SPIKEVAX is a vaccine which stimulates the body's natural defences (immune system). The

vaccine works by causing the body to produce protection (antibodies) against the virus that causes COVID-19 disease. SPIKEVAX uses a substance called messenger ribonucleic acid (mRNA) to carry instructions to cells in the body that are used to make the spike protein that is also on the virus. The cells then make antibodies against the spike protein to help fight off the virus. This will help to protect you against COVID-19 disease.

SPIKEVAX is used to prevent COVID-19 disease caused by SARS-CoV-2. It is given to individuals aged 18 years and older.

2. What should I know before I am given SPIKEVAX?

Warnings

You should not be given SPIKEVAX if:

- you are allergic to Elasomeran or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can be given this vaccine.

Check with your doctor, pharmacist, or nurse before vaccination if you:

- Have previously had a severe, life-threatening allergic reaction after any other vaccine injection or after you were given SPIKEVAX in the past.
- Have a very weak or compromised immune system.

- Have ever fainted following any needle injection.
- Have a bleeding disorder.
- Have a high fever or severe infection; however, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- Have any serious illness.
- Have anxiety related to injections. Anxiety and stress related reactions can occur, however, they will be temporary.
- Take any medicines for any other condition.

Very rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been reported after vaccination with SPIKEVAX. The cases have primarily occurred within two weeks following vaccination, more often after the second vaccination, and more often occurred in younger men. 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor, pharmacist, or nurse if you are

pregnant or intend to become pregnant.

Talk to your doctor, pharmacist, or nurse if you are breastfeeding or intend to breastfeed.

Use in Children

SPIKEVAX is not recommended for children and adolescents aged under 18 years.

3. What if I am taking other medicines?

Tell your doctor, pharmacist, or nurse if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Tell your doctor or pharmacist if you have recently received any other vaccine.

Check with your doctor, pharmacist, or nurse if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SPIKEVAX.