



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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 COVID-19 VACCINE

Active ingredients: *Elasomeran and davesomeran*

Consumer Medicine Information

This vaccine has **provisional approval** in Australia as a booster dose to prevent COVID-19 disease caused by SARS-CoV-2 virus in individuals 12 years and older who have previously received at least a primary vaccination course against COVID-19. This approval has been granted on the basis of immunogenicity and short term safety data. Evidence of longer term benefits 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 BIVALENT ORIGINAL/OMICRON BA.4-5. **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 this medicine.**

Where to find information in this leaflet:

1. Why am I being given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5?

2. What should I know before I am given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5?

3. What if I am taking other medicines?

4. How will I be given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5?

5. What should I know about being given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5?

6. Are there any side effects?

7. Product details

1. Why am I being given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5?

SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 contains the active ingredients elasomeran and davesomeran. SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 is a vaccine which stimulates the body's natural defenses (immune system). The vaccine works by causing the body to produce protection (antibodies) against the virus that causes COVID-19 disease. It 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 BIVALENT ORIGINAL/OMICRON BA.4-5 is used as a booster dose to prevent COVID-19 disease caused by SARS-CoV-2. It is given to individuals aged 12 years and older who have previously received at least a primary vaccination course against COVID-19.