

SPIKEVAX BIVALENT ORIGINAL/OMICRON COVID-19 VACCINE

Active ingredients: Elasomeran and imelasomeran

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 18 years and older. 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. **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?
2. What should I know before I am given SPIKEVAX BIVALENT ORIGINAL/OMICRON?
3. What if I am taking other medicines?
4. How will I be given SPIKEVAX BIVALENT ORIGINAL/OMICRON?
5. What should I know about being given SPIKEVAX

BIVALENT ORIGINAL/OMICRON?

6. Are there any side effects?

7. Product details

1. Why am I being given SPIKEVAX BIVALENT ORIGINAL/OMICRON ?

SPIKEVAX BIVALENT ORIGINAL/OMICRON contains the active ingredients elasomeran and imelasomeran.

SPIKEVAX BIVALENT ORIGINAL/OMICRON 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 is used as a booster dose to prevent COVID-19 disease caused by SARS-CoV-2. It is given to individuals aged 18 years and older.