

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

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about being given this vaccine, speak to your healthcare provider.

▼ This vaccine is new or being used differently. Please report side effects. See the [full CMI](#) for further 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. It is a vaccine used as a booster dose to prevent COVID-19 disease caused by SARS-CoV-2 in individuals aged 12 years and older.

For more information, see Section [1. Why am I being given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5?](#) in the full CMI.

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

You should not be given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 if you have ever had an allergic reaction to SPIKEVAX (original), SPIKEVAX BIVALENT ORIGINAL/OMICRON (BA.1), SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 or any of the ingredients listed at the end of the CMI.

Check with your doctor, pharmacist, or nurse before vaccination if you: have previously had a severe allergic reaction after any vaccine injection in the past; have a very weak or poorly functioning immune system; have ever fainted following any needle injection; have a bleeding disorder; have a high fever or severe infection; have any serious illness; have anxiety related to injections.

Talk to your doctor if you have a weakened immune system, have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 should not be given to children under the age of 12 years.

For more information, see Section [2. What should I know before I am given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription. Tell your doctor or pharmacist if you have recently received any other vaccine. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

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

Your doctor, pharmacist or nurse will inject the vaccine into a muscle (intramuscular injection) in your upper arm. SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 may be given as a booster dose at least 3 months following a primary series and / or previous booster dose with SPIKEVAX (original), SPIKEVAX BIVALENT ORIGINAL/OMICRON (BA.1) or another authorized / approved COVID-19 vaccine. A doctor, pharmacist or nurse will observe you for at least 15 minutes after being given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5.

More instructions can be found in Section [4. How will I be given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5?](#) in the full CMI.

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

Things you should know	<ul style="list-style-type: none">As with any vaccine, SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 may not fully protect all those who receive it and it is not known how long you will be protected.
Driving or using machines	<ul style="list-style-type: none">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.

For more information, see Section [5. What should I know after being given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5?](#) in the full CMI.

6. Are there any side effects?

Common side effects include swelling in the underarm, headache, nausea, vomiting, muscle aches, joint aches, and stiffness, pain or swelling at the injection site, feeling very tired, chills, fever, rash, redness, or hives at the injection site.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This vaccine 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

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.

Consumer Medicine Information (CMI)

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.

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

Warnings

You should not be given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 if:

- you are allergic to elasomeran or davesomeran, 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 (original), SPIKEVAX BIVALENT ORIGINAL/OMICRON (BA.1) or SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 in the past.
- Have a very weak or poorly functioning 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.

There is an increased risk for myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with SPIKEVAX (original), SPIKEVAX BIVALENT ORIGINAL/OMICRON (BA.1) or SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5. These conditions can develop within just a few days after vaccination, and have primarily occurred within two weeks. They are seen more often after the second vaccination, and more often occurred in younger men; however, they are also seen in a number of women. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, a

noticeably rapid, strong, or irregular heartbeat and chest pain. Additionally, non-specific signs such as feeling very tired, nausea and vomiting, stomach pain, dizziness or fainting, fluid retention and cough have been reported in some recipients with myocarditis or pericarditis. 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?](#)

Capillary leak syndrome (CLS) flare-ups

A few cases of capillary leak syndrome flare-ups (causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint, low blood pressure) have been reported following vaccination with SPIKEVAX (original). If you have previously had episodes of CLS, talk to a doctor before you are given SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5.

If you have a weakened immune system (immunocompromised)

The efficacy of SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 may be lower in people who have weaker immune systems. In these cases, you should continue to maintain physical precautions such as mask wearing and social distancing to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Pregnancy and breastfeeding

SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 can be used during pregnancy. A large amount of information from pregnant women vaccinated with SPIKEVAX (original) during the second and third trimester has not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen.

Check with your doctor, pharmacist, or nurse if you are pregnant or intend to become pregnant.

SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 can be given during breastfeeding. A large amount of information from breastfeeding women vaccinated with SPIKEVAX (original) has not shown negative effects in breastfed babies.

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

Use in Children

SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 is not recommended for children aged under 12 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 BIVALENT ORIGINAL/OMICRON BA.4-5.

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

How much SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 is given

- SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 will be given to you as an injection.
- Your doctor, pharmacist or nurse will inject the vaccine into a muscle (intramuscular injection) in your upper arm.
- After the injection of the vaccine, your doctor, pharmacist, or nurse will watch over you for at least **15 minutes** to monitor for signs of an allergic reaction.

If you use too much SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5

- As SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 is given under the close supervision of a doctor, pharmacist, or nurse it is unlikely that you will be given too much.
- If you are concerned that you have been given too much SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5, tell your doctor, pharmacist, or nurse immediately.

You should do this even if there are no signs of discomfort or poisoning.

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

Things you should know

As with any vaccine, SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 may not completely protect all those who receive it and it is not known how long you will be protected.

Driving or using machines

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.

Looking after your vaccine

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

6. Are there any side effects?

All vaccines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, pharmacist, or nurse if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Swelling in the underarm• Headache• Nausea• Vomiting• Muscle ache, joint aches, and stiffness• Heavy menstrual (period) bleeding• Pain or swelling at the injection site• Feeling very tired• Chills• Fever• Rash• Rash, redness, or hives at the injection site (some of which may occur sometime after the injection)	<p>Speak to your doctor, pharmacist, or nurse if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• 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• Decreased sense of touch or sensation• Tingling, pricking or pins and needles feeling	<p>Call your doctor, pharmacist, or nurse straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor, pharmacist, or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

7. Product details

What SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 contains

Active ingredients	Elasomeran and davesomeran
Other ingredients (Inactive ingredients)	<ul style="list-style-type: none">• Heptadecan-9-yl 8-[2-hydroxyethyl-(6-oxo-6-undecyloxyhexyl)amino]octanoate• Cholesterol• Distearoylphosphatidylcholine• 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000• Trometamol• Trometamol hydrochloride• Acetic acid• Sodium acetate trihydrate• Sucrose• Water for injections

Do not take this vaccine if you are allergic to any of these ingredients.

What SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 looks like

SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 is a white to off white suspension supplied in a glass vial with a rubber stopper and a plastic flip-off cap with aluminum seal or in a pre-filled syringe:

0.1 mg/ml vial (AUST R 399552)

0.1 mg/ml pre-filled syringe (AUST R 399553)

Not all presentations may be marketed.

Sponsor

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