TECVAYLI®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the full CMI for further details.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using TECVAYLI?

TECVAYLI is a cancer medicine that contains the active ingredient teclistamab.

TECVAYLI is used to treat adults with cancer of the bone marrow called multiple myeloma. It is used for patients who have had at least three other kinds of treatment which have not worked or have stopped working.

For more information, see Section 1. Why am I using TECVAYLI? in the full CMI.

2. What should I know before I use TECVAYLI?

Do not use if you have ever had an allergic reaction to teclistamab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have had a stroke or seizure within the past 6 months or have had a recent vaccination or are going to have a vaccination.

Tell your doctor if you notice any new or worsening symptoms of Progressive Multifocal Leukoencephalopathy or have ever had hepatitis B infection or might now have hepatitis B infection.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use TECVAYLI? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TECVAYLI and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is TECVAYLI given?

Your doctor or other healthcare professional will give the injection under the skin (called subcutaneous injection) in the stomach area or thigh. More information can be found in Section 4. How is TECVAYLI given? in the full CMI.

5. What should I know while using TECVAYLI?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using TECVAYLI. • Look out for serious side effects such as signs of a condition known as 'cytokine release syndrome' (CRS), infection, 'immune effector cell-associated neurotoxicity syndrome' (ICANS)
Things you should not do	• Do not receive live vaccines within 4 weeks before, during, or 4 weeks after treatment with TECVAYLI
Driving or using machines	• Do not drive, use tools, or operate heavy machinery.
Looking after your medicine	• TECVAYLI will be stored refrigerated at the hospital or clinic. • Do not use this medicine after the expiry date which is stated on the carton after “EXP”.

For more information, see Section 5. What should I know while using TECVAYLI? in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are: serious immune reaction called 'cytokine release syndrome'; low level of antibodies (hypogammaglobulinaemia); low levels of a type of white blood cells (neutropenia); infection; and serious immune reaction called 'immune effector cell-associated neurotoxicity syndrome' that have effects on your nervous system. 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 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.

WARNING: TECVAYLI may cause side effects that are serious, life-threatening or lead to death including Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). Call your healthcare professional right away if you develop any of the signs or symptoms listed below:

- **CRS: fever, nausea, headache, fast heartbeat, feeling dizzy, and difficulty breathing**
- **Neurologic toxicity, including ICANS: headache, feeling confused, feeling less alert, speaking slowly, having difficulty writing, reading and understanding words.**

TECVAYLI®

Active ingredient(s): *teclistamab*

TECVAYLI as monotherapy has **provisional approval** in Australia and is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. The decision to approve this medicine has been made on the basis of promising results from preliminary study. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I using TECVAYLI?

TECVAYLI is a cancer medicine that contains the active ingredient teclistamab.

TECVAYLI is a prescription medication for adults with cancer of the bone marrow, called multiple myeloma.

- It is used for patients who have had at least three other kinds of treatment.
- These treatments have not worked or have stopped working.

TECVAYLI is given alone to treat multiple myeloma.

TECVAYLI is an antibody, which is a type of protein. It has been designed to recognise and attach to specific targets in your body.

TECVAYLI targets proteins found on cells in the blood:

- BCMA (B cell maturation antigen), found on cancer cells
- CD3 (cluster of differentiation 3), found in your immune system

TECVAYLI works by attaching to these proteins so that your immune system can destroy the multiple myeloma cancer cells.

2. What should I know before I use TECVAYLI?

Warnings

Do not use TECVAYLI if:

- you are allergic to teclistamab or any of the ingredients listed at the end of this leaflet.

Check with your healthcare professional if you:

- have had a recent vaccination or are going to have a vaccination
  Do not receive live vaccines:
  - four weeks before beginning treatment with TECVAYLI
  - during treatment with TECVAYLI
  - four weeks after your final dose of TECVAYLI.
- have had a stroke or seizure within the past 6 months
- notice any new or worsening symptoms of Progressive Multifocal Leukoencephalopathy (PML). PML is a serious and potentially fatal brain infection. Symptoms may include, but are not limited to, blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion.
- have ever had or might now have hepatitis B infection. This is because TECVAYLI could cause hepatitis B virus to become active again. Your healthcare professional will check you for signs of this infection before, during and for some time after treatment with TECVAYLI. Tell your healthcare professional if you get worsening

tiredness, or yellowing of your skin or white part of your eyes.

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 if you or your partner are pregnant or intend to become pregnant.
    - Men: if your partner could become pregnant, you must use effective contraception during and for 3 months after stopping treatment with TECVAYLI. If your partner becomes pregnant while you are being treated with this medicine, tell your doctor right away.
    - Women: you must use effective contraception during and for 5 months after stopping treatment with TECVAYLI. If you become pregnant while being treated with this medicine, tell your doctor right away.
- You and your doctor will decide if the benefit of breastfeeding is greater than the risk to your baby. If you and your doctor decide to stop taking this medicine, you should not breastfeed for 5 months after stopping treatment.

Children and Adolescents

- Do not give TECVAYLI to children or young people below 18 years of age. This is because it is not known how the medicine will affect them.

3. What if I am taking other medicines?

Some medicines may interfere with TECVAYLI and affect how it works.

Tell your doctor or pharmacist 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.

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

4. How is TECVAYLI given?

How much to use

Your doctor or healthcare professional will work out your dose of TECVAYLI based on your body weight.

The recommended dose of TECVAYLI is:

- First dose - 0.06 mg for each kilogram of body weight
- Second dose - 0.3 mg for each kilogram of body weight
- Treatment dose - 1.5 mg for each kilogram of body weight

TECVAYLI is given as follows:

- You will receive your First dose of TECVAYLI to begin treatment
- You will receive your Second dose 2-4 days later
- You will then receive a 'Treatment dose' 2-4 days after your second dose
- You will continue receiving a 'Treatment dose' once a week for as long as you are getting benefit from TECVAYLI

If you are continuing to receive benefit from TECVAYLI after 6 months, your doctor may decide that you can change to receive the 'Treatment dose' at a reduced frequency (every two weeks).

Your healthcare professional will monitor you for side effects after each of your first three doses - they will do this for 2 days after each dose. You should stay near a healthcare facility after each of the first three doses in case you have side effects. Your healthcare professional will tell you if you need to be monitored after other doses.

How to use TECVAYLI

TECVAYLI will be given to you by your healthcare professional as an injection under the skin (subcutaneous injection) in the stomach area or thigh.

Before you have TECVAYLI your healthcare professional will check:

- Your blood counts
- For signs of infection - an infection will be treated before you have TECVAYLI
- If you are pregnant or breastfeeding

After you have TECVAYLI your healthcare professional will:

- Monitor you for side effects
- Regularly check your blood counts, as the number of blood cells and other blood components may decrease

Medicines given during treatment with TECVAYLI

Before each of your first three injections of TECVAYLI, you will be given medicines to help lower the chance of side effects. These may include:

- Medicines for an allergic reaction (antihistamines)
- Medicines for inflammation (corticosteroids)
- Medicines for fever (such as paracetamol)

You may be given these medicines for later doses of TECVAYLI based on any symptoms you have.

You may be given additional medicines based on any symptoms you experience or your medical history.

If you forget to use TECVAYLI

If you cannot keep your appointment with the doctor, make sure you call your doctor right away so another appointment can be made as soon as possible.

If you use too much TECVAYLI

This medicine will be given by your healthcare professional. In the unlikely event that you are given too much (an overdose) your healthcare professional will check you for side effects.

5. What should I know while using TECVAYLI?

Things you should do

Follow your doctor's instructions carefully.

Tell your doctor if you become pregnant or intend to become pregnant.

Call your doctor straight away if you experience any of the following:

- Signs of a condition known as 'cytokine release syndrome' (CRS). A patient card to inform you of CRS is available from your doctor and you need to always carry this card with you whilst on treatment.
- Effects on your nervous system, which can occur days or weeks after you receive the injection, and may initially be subtle. Some of these may be signs of a serious immune reaction called 'immune effector cell-associated neurotoxicity syndrome' (ICANS).
- Signs and symptoms of an infection.

Tell your healthcare professional if you notice any signs of the above. The symptoms are listed under "Serious side effects" in Section 6. Are there any side effects.

Remind any doctor, dentist or pharmacist you visit that you are using TECVAYLI.

Driving or using machines

Some people may feel tired, dizzy, or confused while taking TECVAYLI. Do not drive, use tools, or operate heavy machinery. Also, do not do things that could pose a danger to yourself.

Wait until at least 48 hours after receiving your third dose of TECVAYLI or as instructed by your doctor.

Looking after your medicine

TECVAYLI is stored and administered by healthcare professionals so it is unlikely that you will store this medicine at home.

TECVAYLI should be stored in a refrigerator (2°C-8°C) and kept in the original carton in order to protect from light. Do not freeze.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

TECVAYLI will be disposed of appropriately by the healthcare professionals.

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

6. Are there any side effects?

All medicines 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 or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• decreased appetite • nausea, diarrhoea, constipation, vomiting, abdominal pain • headache • fever • feeling very tired • nerve damage that may cause tingling, numbness, pain or loss of pain sensation • pain or muscle aches • muscle spasms • bleeding, which can be severe (haemorrhage) • swollen hands, ankles or feet (oedema) • lung infection (pneumonia) • infected nose, sinuses or throat (upper respiratory tract infection) • skin infection causing redness (cellulitis) • urinary tract infection • skin reactions at or near the injection site, including redness of the skin, itching, swelling, pain, bruising, rash, bleeding • low level of oxygen (hypoxia) • being short of breath (dyspnoea) • cough • high blood pressure (hypertension) • low blood pressure (hypotension) Abnormal blood test results such as: • a low levels of red blood cells (anaemia) • low levels of 'platelets' (cells that help blood to clot) • low number of white blood cells (leukopenia) • low levels of a type of white blood cells (lymphopenia) • low level of 'phosphate', 'magnesium' or 'potassium' in the blood (hypophosphataemia, hypomagnesaemia or hypokalaemia) • increased level of 'calcium' (hypercalcaemia) • increased 'alkaline phosphatase' in the blood	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• low level of 'calcium' or 'sodium' in the blood (hypocalcaemia or hyponatraemia) • high level of 'potassium' in the blood (hyperkalaemia) • low level of 'albumin' in the blood (hypoalbuminaemia) • low level of sugar in the blood (hypoglycaemia) • increased level of 'gamma-glutamyltransferase' in the blood (blood gamma-glutamyltransferase increase) • increased level of liver enzymes 'transaminases' in the blood (blood transaminase increase) • increased level of 'creatinine' in the blood (blood creatinine increase) • increased level of 'amylase' in the blood (hyperamylasaemia) • increased level of 'lipase' in the blood (hyperlipasemia)	

Serious side effects

Serious side effects	What to do
• serious immune reaction that may cause fever, nausea, headache, fast heart beat, feeling dizzy, and difficulty breathing ('cytokine release syndrome') • low level of antibodies called 'immunoglobulins' in the blood, which may make infections more likely (hypogammaglobulinaemia) • low levels of a type of white blood cells (neutropenia) • low number of a type of white blood cell (neutrophils) with a fever • infection, which may include fever, chills, shivering, cough, shortness of breath, rapid breathing and rapid pulse • severe infection throughout the body (sepsis) • COVID-19 infection caused by a virus called coronavirus (SARS-CoV-2) • effects on your nervous system, which may include headache, feeling confused, feeling less alert, speaking slowly, having difficulty writing, reading and understanding words. Some of these symptoms may be signs of a serious immune reaction called 'immune effector cell-associated neurotoxicity syndrome' (ICANS) • change in brain function (encephalopathy) • A serious and potentially fatal brain infection called Progressive Multifocal Leukoencephalopathy (PML). Some of the symptoms include blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation and memory loss or confusion.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist 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 medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TECVAYLI contains

Active ingredient (main ingredient)	teclistamab
Other ingredients (inactive ingredients)	disodium edetate (EDTA) glacial acetic acid polysorbate 20 sodium acetate trihydrate sucrose water for injections

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

What TECVAYLI looks like

TECVAYLI is a solution for injection and is a colourless to light yellow liquid.

TECVAYLI is supplied as a carton pack containing 1 glass vial.

- teclistamab 30 mg/3 mL (10 mg/mL) AUST R 387621
- teclistamab 153 mg/1.7 mL (90 mg/mL) AUST R 387622

Who distributes TECVAYLI

Janssen-Cilag Pty Ltd

17 Khartoum Road Macquarie Park NSW 2113

Australia

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

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