

TALVEY®

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 TALVEY?

TALVEY is a cancer medicine that contains the active ingredient talquetamab.

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

For more information, see Section [1. Why am I using TALVEY?](#) in the full CMI.

2. What should I know before I use TALVEY?

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

Talk to your doctor if you have had a recent vaccination or are going to have a vaccination. 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 TALVEY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TALVEY 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 TALVEY 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 TALVEY given?](#) in the full CMI.

5. What should I know while using TALVEY?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you are using TALVEY. • Look out for serious side effects such as signs of a conditions known as 'cytokine release syndrome' (CRS), infection and 'immune effector cell-associated neurotoxicity syndrome' (ICANS).
Things you should not do	<ul style="list-style-type: none"> • Do not receive live vaccines within 4 weeks before, during, or 4 weeks after treatment with TALVEY.
Driving or using machines	<ul style="list-style-type: none"> • Do not drive, use tools, or operate heavy machinery.
Looking after your medicine	<ul style="list-style-type: none"> • TALVEY 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”.
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For more information, see Section [5. What should I know while using TALVEY?](#) 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 levels of a type of white blood cells (neutropenia); low number of ‘platelets’ (thrombocytopenia); problems with the mouth and swallowing; infections that may cause fever, chills, shivering, cough shortness of breath, rapid breathing and rapid pulse; skin problems; 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: TALVEY 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, low blood pressure, chills, difficulty breathing, fatigue, headache, fast heartbeat.**
- **Neurologic toxicity, including ICANS: feeling confused, feeling less alert, feeling disorientated, feeling sleepy, slow or difficulty thinking, altered thinking or decreased consciousness, confusion, difficulty speaking and understanding speech.**

TALVEY

Active ingredient(s): *talquetamab*

This medicine has **provisional registration** in Australia for the treatment of adult patients with relapsed or refractory multiple myeloma, who have previously received at least four prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and

an anti-CD38 antibody. The decision to provisionally register this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to substantiate the benefit of the medicine for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about using TALVEY. **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 TALVEY.**

Where to find information in this leaflet:

1. Why am I using TALVEY?
2. What should I know before I use TALVEY?
3. What if I am taking other medicines?
4. How is TALVEY given?
5. What should I know while using TALVEY?
6. Are there any side effects?
7. Product details

1. Why am I using TALVEY?

TALVEY is a cancer medicine that contains the active ingredient talquetamab.

TALVEY 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 four other kinds of treatment.
- These treatments have not worked or have stopped working.

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

TALVEY targets proteins found on cells in the blood:

- GPRC5D (G Protein-coupled receptor family C group 5 member D), found on multiple myeloma cancer cells, and
- CD3 (cluster of differentiation 3), found in your immune system.

TALVEY 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 TALVEY?

Warnings

Do not use TALVEY if:

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

Always check the ingredients to make sure you can use this medicine.

Check with your doctor 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 TALVEY
 - during treatment with TALVEY
 - four weeks after your final dose of TALVEY.

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.
 - If you or your partner could become pregnant, you must use effective contraception during and for 3 months after stopping treatment with TALVEY.
 - For women - if you become pregnant while being treated with this medicine, tell your doctor right away. It is unknown how TALVEY may affect your unborn baby.
 - For men - if your partner becomes pregnant while you are being treated with this medicine, tell your doctor right away.
- Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if TALVEY passes into breast milk. You and your doctor will decide if the

benefit of breastfeeding is greater than the risk to your baby.

Children and Adolescents

Do not give TALVEY 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 TALVEY 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 TALVEY.

4. How is TALVEY given?

How much to use

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

TALVEY is given either once a week or once every 2 weeks as follows:

0.4 mg/kg once a week:

- First dose - 0.01 mg for each kilogram of body weight.
- Second dose - 0.06 mg for each kilogram of body weight 2 - 4 days after your first dose
- Treatment dose - 0.4 mg for each kilogram of body weight 2 - 4 days after your second dose
- Continue receiving a Treatment dose once a week.

Treatment will continue for as long as you are getting benefit from TALVEY.

Your doctor or 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 close to a healthcare facility after each of the first three doses in case you have side effects.

0.8 mg/kg once every 2 weeks:

- First dose - 0.01 mg for each kilogram of body weight.
- Second dose - 0.06 mg for each kilogram of body weight 2 - 4 days after your first dose
- Third dose - 0.4 mg for each kilogram of body weight 2 - 4 days after your second dose
- Treatment dose - 0.8 mg for each kilogram of body weight 2 - 4 days after your third dose
- Continue receiving a Treatment dose once every 2 weeks.

Treatment will continue for as long as you are getting benefit from TALVEY.

Your doctor or healthcare professional will monitor you for side effects after each of your first four doses. They will do this for 2 days after each dose. You should stay

close to a healthcare facility after each of the first four doses in case you have side effects.

How to use TALVEY

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

Before you have TALVEY your doctor or healthcare professional will check:

- your blood counts
- for signs of infection - an infection will be treated before you have TALVEY
- if you are pregnant or breastfeeding.

After you have TALVEY your doctor or 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 TALVEY

Before the first three doses of the 0.4 mg/kg dosing schedule or the first four doses of the 0.8 mg/kg dosing schedule of TALVEY, you will be given medicines which help to 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 TALVEY 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 TALVEY

It is very important to go to all your appointments to make sure your treatment works. If you cannot keep your appointment with the doctor or healthcare professional, make sure you call your doctor right away so another appointment can be made as soon as possible.

If you use too much TALVEY

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

5. What should I know while using TALVEY?

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)
- 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.

A Patient Card to inform you of CRS and neurologic toxicity, including ICANS is available from your doctor, and you need to always carry this card with you whilst on treatment.

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 TALVEY.

Driving or using machines

Some people may feel tired, dizzy, or confused while using TALVEY. Do not drive, use tools, or operate heavy machinery or do things that could pose a danger to yourself until at least 48 hours after receiving your first dose of TALVEY or as instructed by your doctor.

Looking after your medicine

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

TALVEY 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

TALVEY 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
<ul style="list-style-type: none">• decreased appetite• diarrhoea, nausea, or constipation• abdominal pain• vomiting• weight loss• nail problems• muscle and joint pain• mouth pain• pain• feeling very tired• irritation or pain where the injection is given• itching• abnormally dry skin that may affect the protective linings of the body (such as the mouth and eyes)• swelling caused by fluid build up in the body (oedema)• feeling dizzy• problem being able to produce or control movement	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • nerve damage that may cause tingling, numbness, pain or loss of pain sensation • low level of antibodies called 'immunoglobulins' in the blood, which may make infections more likely • infected nose, sinuses or throat (cold) • COVID-19 infection caused by a virus called coronavirus (SARS-CoV-2) • bacterial infection • fungal infection • lung infection (pneumonia) • viral infection • change in brain function (encephalopathy) <p>Abnormal blood test results such as:</p> <ul style="list-style-type: none"> • low number of a type of white blood cells (lymphocytes) 	

Less serious side effects	What to do
<ul style="list-style-type: none"> • low number of white blood cells (leukopenia) • increased level of liver enzymes 'transaminases' in the blood (blood transaminase increase) • low number of red blood cells (anaemia) • low level of 'potassium' or 'phosphate' in the blood (hypophosphataemia or hypokalaemia) • low levels of magnesium in the blood (hypomagnesaemia) 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • serious immune reaction called 'cytokine release syndrome' (CRS) that may cause fever, low blood pressure, chills, low level of oxygen in the blood, headache, and fast heart beat 	<p>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.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • low levels of a type of white blood cells (neutropenia) • low number of 'platelets' (cells that help blood to clot, thrombocytopenia) • problems with the mouth and swallowing, such as change in sense of taste, dry mouth, difficulty swallowing, and sores in the mouth • infection, which may include fever, chills, shivering, cough, shortness of breath, rapid breathing and rapid pulse • severe infection throughout the body (sepsis) • skin problems, such as skin rash • effects on your nervous system, which may include feeling confused, less alert or aware, feeling disoriented, feeling 	

Serious side effects	What to do
<p>sleepy with low energy, slow and difficulty thinking, difficulty with coordination affecting movement, balance, and speech, fast eye movements that cannot be controlled. Some of these symptoms may be signs of a serious immune reaction called 'immune effector cell-associated neurotoxicity syndrome' (ICANS)</p>	

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 TALVEY contains

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

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

What TALVEY looks like

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

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

- talquetamab 3 mg/1.5 mL (2 mg/mL) AUST R 409913
- talquetamab 40 mg/1.0 mL (40 mg/mL) AUST R 409912

Who distributes TALVEY

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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