

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

TALVEY™

(talquetamab injection)

Read this carefully before you receive **Talvey (Tal' vay)**. This is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Talvey**.

Serious Warnings and Precautions

- Fever and chills which may be symptoms of a serious side effect called cytokine release syndrome (CRS), which can be severe or fatal. Other symptoms of CRS may include difficulty in breathing, dizziness or feeling light-headed, feeling the need to throw up, headache, fast heartbeat, low blood pressure, feeling tired, vomiting, muscle pain and joint pain.
- Neurologic problems which may include symptoms like headache, confusion, difficulty with memory, difficulty speaking or slow speech, difficulty understanding speech, difficulty in writing, confused about time or surroundings, being less alert, or excessive sleepiness, and seizures (fits) which can be serious or life-threatening. Some of these may be signs of a serious immune reaction called 'immune effector cell associated neurotoxicity syndrome' (ICANS). These effects can occur days or weeks after you receive the injection, and may initially be subtle.
- Your healthcare provider will monitor for signs and symptoms of CRS and neurological problems during treatment with Talvey. You should call your healthcare provider right away if you develop any of the signs and symptoms of CRS or neurologic problems at any time during your treatment with Talvey.

What is Talvey used for?

Talvey is used to treat patients with a type of cancer of the bone marrow called multiple myeloma. It is given when your cancer has not responded to or has come back after at least three different treatments, and your cancer is not responding to your most recent therapy. Talvey is given alone to treat multiple myeloma.

For the following indication Talvey has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

- The treatment of adult patients with relapsed or refractory multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on or after the last therapy.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How does Talvey work?

Talvey is a cancer medicine that contains the active substance 'talquetamab'.

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.

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

What are the ingredients in Talvey?

Medicinal ingredients: talquetamab

Non-medicinal ingredients: EDTA disodium salt dihydrate, glacial acetic acid, polysorbate 20, sodium acetate trihydrate, sucrose, and water for injection.

Talvey comes in the following dosage forms:

Talvey comes in 2 different strengths:

- Talquetamab 3 mg/1.5 mL (2 mg/mL)
- Talquetamab 40 mg/1.0 mL (40 mg/mL)

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.

Do not use Talvey if:

If you are allergic to talquetamab or any of the other ingredients of this medicine (listed in “What are the ingredients in Talvey?”). If you are not sure, talk to your healthcare professional before you receive Talvey.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive Talvey. Talk about any health conditions or problems you may have, including if you:

- Have an infection, or had an infection with hepatitis virus in the past. An infection will be treated before you receive Talvey.
- Have had a stroke or seizure, or any other types of neurological problems within the past 6 months.
- Have had a recent vaccination or are going to have a vaccination. You should not receive live vaccines four weeks before, during, or four weeks after your final dose of Talvey.
- Are pregnant, think you might be pregnant, or plan to become pregnant. If you or your partner could become pregnant, you must use effective contraception during treatment and for 3 months after stopping treatment with Talvey. If you or your partner become pregnant while being treated with this medicine, tell your healthcare professional right away.
- Are breast-feeding or plan to breast-feed. It is not known if Talvey passes into breast milk. Ask your healthcare professional for advice before receiving this medicine. You and your healthcare professional will decide if the benefit of breast-feeding is greater than the risk to your baby.

Other warnings you should know about:

Driving and using machines:

- Some people may feel tired, dizzy, or confused while taking Talvey. Do not drive, use tools, or operate heavy machinery or do things that could pose a danger to you or others in the 48 hours after receiving your first three (0.4 mg/kg dosing schedule) or four (0.8 mg/kg dosing schedule) doses of Talvey, or until instructed by your healthcare professional.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Interactions with other drugs, vitamins, minerals, natural supplements or alternative medicines have not been established with Talvey.

How you will receive Talvey:

Talvey will be given to you by a healthcare professional in a healthcare setting. Talvey will be given to you by a healthcare professional as an injection under your skin ('subcutaneous' injection). It is given in the stomach area (abdomen) or thigh.

Before you receive Talvey your 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 breast-feeding

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

After you receive Talvey 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

Usual dose:

Your healthcare professional will determine your dose of Talvey. The dose of Talvey will depend 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:

- You will receive 0.01 mg for each kilogram of bodyweight for your first dose.
- You will receive 0.06 mg per kilogram of bodyweight as your second dose 2-4 days later.
- You will then receive a 'Treatment dose' of 0.4 mg per kilogram of bodyweight 2-4 days after your second dose.
- You will then continue receiving a 'Treatment dose' once a week.
- Treatment will continue for as long as you are getting benefit from Talvey.

Your healthcare professional will monitor you for side effects for 2 days after each of your first three doses. You should stay close to a healthcare facility after each of the first three doses in case you have side effects. Your healthcare professional may decide to hospitalize you after each of the first three doses. Your healthcare professional will tell you if you need to be monitored after other doses.

0.8 mg/kg once every 2 weeks:

- You will receive 0.01 mg for each kilogram of bodyweight for your first dose.
- You will receive 0.06 mg per kilogram of bodyweight as your second dose 2-4 days later.
- You will receive 0.4 mg per kilogram of bodyweight as your third dose 2-4 days later.
- You will then receive a 'Treatment dose' of 0.8 mg per kilogram of bodyweight 2-4 days after your third dose.
- You will then continue receiving a 'Treatment dose' once every 2 weeks.
- Treatment will continue for as long as you are getting benefit from Talvey.

Your healthcare professional will monitor you for side effects for 2 days after each of your first four doses. You should stay close to a healthcare facility after each of the first four doses in case you have side effects. Your healthcare professional may decide to hospitalize you after each of the first four doses. Your healthcare professional will tell you if you need to be monitored after other doses.

Overdose:

Talvey will be given by your healthcare professional. In the event that you receive too much (an overdose), your healthcare professional will check you for side effects.

If you think you, or a person you are caring for, have received too much Talvey, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

It is very important to go to all your appointments to make sure your treatment works. If you miss an appointment, make another one as soon as possible.

What are possible side effects from using Talvey?

Like all medicines, this medicine can cause side effects, although not everybody gets them. These are not all the possible side effects you may have when taking Talvey. If you experience any side effects not listed here, tell your healthcare professional.

Very common (may affect more than 1 in 10 people):

- low level of antibodies called 'immunoglobulins' in the blood, which may make infections more likely

- Nail problems
- Muscle and joint pain
- Low number of red blood cells
- Feeling very tired
- Weight loss
- Low number of a type of white blood cells (lymphocytes)
- Diarrhoea, nausea, or constipation
- Infected nose, sinuses or throat (cold)
- Itching
- Decreased appetite
- Abnormally dry skin that may affect the protective linings of the body (such as the mouth and eyes)
- Pain
- Low number of white blood cells
- Low level of 'potassium' or 'phosphate' in the blood
- Swelling caused by fluid build up in the body
- Irritation or pain where the injection is given
- Increased level of 'transaminases' in the blood
- COVID-19 infection caused by a virus called coronavirus (SARS-CoV-2)
- Bacterial infection
- Problems with the mouth
- Fungal infection
- Nerve damage that may cause tingling, numbness, pain, or loss of pain sensation
- Problems being able to produce or control movement
- Feeling dizzy
- Change in brain function (encephalopathy)
- Abdominal pain
- Vomiting

Common (may affect up to 1 in 10 people):

- Viral infection
- Pneumonia (lung infection)
- Severe infection throughout the body (sepsis)

Get medical help straight away if you get any of the following serious side effects which may be severe and can be fatal.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
VERY COMMON (may affect more than 1 in 10 people)			
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 heartbeat		✓	✓
Low levels of a type of white blood cell (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 that may cause fever, chills, shivering, cough, shortness of breath, rapid breathing, and rapid pulse		✓	✓
Skin problems, such as skin rash		✓	✓
COMMON (may affect up to 1 in 10 people)			
Effects on your nervous system. These may be signs of a serious immune reaction called 'immune effector cell associated neurotoxicity syndrome' (ICANS). Some of the symptoms are feeling confused, being less alert or aware, feeling disoriented, feeling sleepy, feeling sleepy with low energy, and slow and difficulty thinking.		✓	✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Talvey will be stored at the healthcare facility by your healthcare professional.

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

If you want more information about Talvey:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer’s website <https://www.janssen.com/canada>, or by calling 1-800-567-3331.

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