PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTECVAYLI®

(teclistamab injection)

Read this carefully before you receive **Tecvayli** (Tek vay' lee). 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 **Tecvayli**.

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 professional will monitor for signs and symptoms of CRS and neurological problems during treatment with Tecvayli. You should call your healthcare professional right away if you develop any of the signs and symptoms of CRS or neurologic problems at any time during your treatment with Tecvayli.

What is Tecvayli used for?

Tecvayli 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.

Tecvayli is given alone to treat multiple myeloma.

For the following indication Tecvayli 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 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 Tecvayli work?

Tecvayli is a cancer medicine that contains the active substance 'teclistamab'.

Tecvayli is an antibody, which is a type of protein. It has been designed to recognize and attach to specific targets in your body. Tecvayli targets the following proteins found on cells in the blood:

- BCMA (B-cell maturation antigen), found on cancer cells, and on some healthy 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.

What are the ingredients in Tecvayli?

Medicinal ingredients: teclistamab

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

Tecvayli comes in the following dosage forms:

Tecvayli comes in two different strengths:

- teclistamab 30 mg/3 mL (10 mg/mL).
- teclistamab 153 mg/1.7 mL (90 mg/mL).

Tecvayli is a solution for injection and is a clear to slightly opalescent, colourless to light yellow liquid. Tecvayli is supplied as a carton pack containing 1 glass vial.

Do not use Tecvayli if:

You are allergic to Tecvayli or any of the other ingredients of this medicine (listed in "What are the ingredients in Tecvayli"?). If you think you may be allergic, ask your doctor for advice.

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

- have an infection, or have ever had or might now have a 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.
- have had a stroke or seizure, or any other types of neurological problems 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 had a recent vaccination or are going to have a vaccination.
- are pregnant, think you might be pregnant or are planning a baby. If you could become pregnant, you must use effective contraception during and for 5 months after stopping treatment with Tecvayli. If your partner could become pregnant, you must use effective contraception during and for 3 months after stopping treatment with Tecvayli. If you or your partner become pregnant while being treated with this medicine, tell your healthcare professional right away.

- are producing breastmilk. 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.

Other warnings you should know about:

Do not receive live vaccines:

- four weeks before beginning treatment with Tecvayli.
- during treatment with Tecvayli.
- four weeks after your final dose of Tecvayli.

Driving and 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 or others.
- Wait until at least 48 hours after receiving your third dose of Tecvayli or as instructed by your doctor.

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 Tecvayli.

How to take Tecvayli:

Tecvayli will be given to you by your healthcare professional. It will be given as an injection under the skin (subcutaneous injection) in your 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.

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 acetaminophen/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.

Usual dose:

Your healthcare professional will determine your dose of Tecvayli. The dose of Tecvayli will depend on your body weight. The recommended dose of Tecvayli is:

- First dose is 0.06 mg for each kilogram of body weight.
- Second dose is 0.3 mg for each kilogram of body weight.
- Treatment dose is 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 start 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.

After you have Tecvayli your healthcare professional will monitor you for side effects and regularly check your blood counts as the number of blood cells and other blood components may decrease.

After each of your first three doses, your healthcare professional will closely monitor you for side effects for 2 days after each dose. You should plan to stay near a healthcare facility after each of the first three doses in case you have side effects. It is also possible that your healthcare professional decides to hospitalize you after each of the first three doses. Your healthcare professional will you tell you if you will need to be monitored after other doses.

Overdose:

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

If you think you, or a person you are caring for, have taken too much Tecvayli, 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. If you miss an appointment, tell your doctor and make another appointment as soon as possible.

What are possible side effects from using Tecvayli?

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 Tecvayli. If you experience any side effects not listed here, tell your healthcare professional.

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

- Infected nose, sinuses or throat (upper respiratory tract infection)
- Low levels of red blood cells (anemia)
- 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 antibodies called 'immunoglobulins' in the blood, which may make infections more likely (hypogammaglobulinemia)
- Low level of 'phosphate', 'magnesium' or 'potassium' in the blood (hypophosphatemia, hypomagnesemia or hypokalemia)
- Increased level of 'calcium' in the blood (hypercalcemia)
- Increased 'alkaline phosphatase' in the blood
- Decreased appetite
- Nausea, diarrhea, constipation or vomiting
- Headache
- Nerve damage that may cause tingling, numbness, pain or loss of pain sensation
- High blood pressure (hypertension)
- Bleeding, which can be severe (hemorrhage)
- Cough
- Being short of breath (dyspnea)
- Fever
- Feeling very tired
- Pain or muscle aches
- Swollen hands, ankles or feet (edema)
- Skin reactions at or near the injection site, including redness of the skin, itching, swelling, pain, bruising, rash, bleeding
- Increased level of 'gamma-glutamyltransferase' in the blood

Common (may affect up to 1 in 10 people)

- Infections caused by herpes viruses including shingles or cold sores
- Low level of 'calcium' or 'sodium'in the blood (hypocalcemia or hyponatremia)
- High level of 'potassium' in the blood (hyperkalemia)
- Low level of 'albumin' in the blood (hypoalbuminemia)
- Increased level of liver enzymes 'transaminases' in the blood
- Increased level of 'creatinine' in the blood and decreased kidney function
- Increased level of 'amylase' in the blood
- Increased level of 'lipase' in the blood

Uncommon (may affect up to 1 in 100 people)

- Viruses may become active again ('viral reactivation' including adenovirus activation, BK virus infection, cytomegalovirus infection)

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON (more than 1 in 10)			
Fever, chills, nausea, headache, fast heartbeat, feeling dizzy, low blood pressure, vomiting, muscle or joint pain, difficulty breathing, low level of oxygen in the blood (all possible symptoms of a serious immune reaction called 'cytokine release syndrome' [CRS]).		√	√
Serious infection, such as lung infections, COVID-19 infection, skin infections, infection in the blood (sepsis). Symptoms may include fever, chills or shivering, cough, shortness of breath, rapid breathing, rapid pulse, red swollen painful area of skin, low blood pressure, liver failure, and respiratory failure.		√	√
Muscle weakness or stiffness, muscle tremors, difficulty writing or speaking, inability to produce movement (all possible symptoms of a condition called 'motor dysfunction').		√	√
Headache, feeling confused, feeling less alert or excessive sleepiness, speaking slowly, having difficulty writing, reading and understanding words, difficulty with memory, fits (seizures), shaking, or weakness with loss of movement on one side of the body (all possible symptoms of serious side effects of the brain, including encephalopathy and in some cases 'immune effector cell-associated neurotoxicity syndrome [ICANS]).		√	√

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
COMMON (less than 1 in 10 but more than 1 in 100)			
Low levels of a type of white blood cells with a fever (febrile neutropenia).		√	√
UNCOMMON (less than 1 in 100 but more than 1 in 1000)			
Feeling very tired, loss of appetite, nausea, vomiting, abdominal pain, a swollen belly, yellowing of your skin or eyeballs, bruising or bleeding, confusion or sleepiness (all possible symptoms of hepatitis and liver failure, as a result of re-activation of hepatitis B virus [HBV] if you have a previous infection with the virus).		√	√
Progressive weakness on one side of the body, clumsiness of limbs, disturbance of vision, changes in thinking, memory and orientation, confusion, personality changes (all possible symptoms of a rare type of brain infection called 'progressive multifocal leukoencephalopathy' [PML]).		√	√

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

Storage

Tecvayli is stored at the hospital or clinic.

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.

If you want more information about Tecvayli:

- 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 www.janssen.com/canada, or by calling 1-800-567-3331 or 1-800-387-8781.

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