Package leaflet: Information for the patient

TECVAYLI 10 mg/mL solution for injection
TECVAYLI 90 mg/mL solution for injection

teclistamab

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What TECVAYLI is and what it is used for

TECVAYLI is a cancer medicine that contains the active substance 'teclistamab' and is used to treat adults with a type of cancer of the bone marrow called multiple myeloma.
It is used for patients who have had at least three other kinds of treatment that have not worked or have stopped working.

How TECVAYLI works
TECVAYLI is an antibody, a type of protein which has been designed to recognise and attach to specific targets in your body. TECVAYLI targets B cell maturation antigen (BCMA), which is found on multiple myeloma cancer cells, and cluster of differentiation 3 (CD3), which is found on so-called T cells of your immune system. This medicine works by attaching to these cells and bringing them together, so that your immune system can destroy the multiple myeloma cancer cells.

2. What you need to know before you are given TECVAYLI

You must not be given TECVAYLI if you are allergic to teclistamab, or any of the other ingredients of this medicine (listed in section 6).
If you are not sure if you are allergic, talk to your doctor or nurse before you are given TECVAYLI.

Warnings and precautions
Talk to your doctor or nurse before you are given TECVAYLI if you have had a stroke or seizure within the past 6 months.

TECVAYLI and vaccines
Talk to your doctor or nurse before you are given TECVAYLI if you have had a recent vaccination or are going to have a vaccination.

You should not receive live vaccines from four weeks before until four weeks after you are treated with TECVAYLI.

Tests and checks
Before you are given TECVAYLI, your doctor will check your blood counts for signs of infection. If you have any infection, it will be treated before you start TECVAYLI. Your doctor will also check if you are pregnant or breast-feeding.

During treatment with TECVAYLI, your doctor will monitor you for side effects. Your doctor will regularly check your blood counts, as the number of blood cells and other blood components may decrease.

Look out for serious side effects.
Tell your doctor or nurse right away if you experience any of the following:
- Signs of a condition known as 'cytokine release syndrome' (CRS). Cytokine release syndrome is a serious immune reaction with symptoms such as fever, chills, nausea, headache, fast heartbeat, feeling dizzy, and difficulty breathing.
- Effects on your nervous system. Symptoms include feeling confused, feeling less alert, or having difficulty writing. 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 doctor or nurse if you notice any signs of the above.

Children and adolescents
Do not give TECVAYLI to children or young people below 18 years of age, because it is not known how this medicine will affect them.

Other medicines and TECVAYLI
Tell your doctor or nurse if you are taking, have recently taken, or might take any other medicines. This includes medicines you can get without a prescription and herbal medicines.

Pregnancy and breast-feeding
It is not known if TECVAYLI affects an unborn baby or if it passes into breast milk.

Pregnancy-information for women
Tell your doctor or nurse before you are given TECVAYLI if you are pregnant, think you might be pregnant or are planning to have a baby.
If you become pregnant while being treated with this medicine, tell your doctor or nurse straight away.

Pregnancy-information for men
If your partner becomes pregnant while you are taking this medicine, tell your doctor straight away.

Contraception
If you or your partner could become pregnant, you must use effective contraception during treatment and for 3 months after stopping treatment with TECVAYLI.

Breast-feeding
You and your doctor will decide if the benefit of breast-feeding is greater than the risk to your baby. If you and your doctor decide to stop taking this medicine, you should not breast-feed for 3 months after stopping treatment.

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

TECVAYLI contains sodium
TECVAYLI contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How TECVAYLI is given

How much is given
Your doctor will determine your dose of TECVAYLI. The dose will depend on your body weight. The first two doses will be lower.

TECVAYLI is given as follows:
- You will receive 0.06 mg for each kilogram of bodyweight for your first dose.
- You will receive 0.3 mg per kilogram of bodyweight as your second dose 2-7 days later.
- You will then receive a 'Maintenance dose' of 1.5 mg per kilogram of bodyweight 2-7 days after your second dose.
- You will then continue receiving a 'Maintenance dose' once a week as long as you are getting benefit from TECVAYLI.

Your doctor 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 the first three doses in case you have side effects.

How the medicine is given
TECVAYLI will be given to you by a doctor or nurse as an injection under your skin ('subcutaneous' injection). It is given in the stomach area (abdomen) or thigh.

Other medicines given during treatment with TECVAYLI
You will be given medicines 1-3 hours before each of your first three doses of TECVAYLI, which help to lower the chance of side effects, such as cytokine release syndrome. These may include:
- medicines to reduce the risk of an allergic reaction (antihistamines)
- medicines to reduce the risk of inflammation (corticosteroids)
- medicines to reduce the risk of fever (such as paracetamol)

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

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

If you are given more TECVAYLI than you should
This medicine will be given by your doctor or nurse, and it is unlikely that you will receive too much. In the event that you are given too much (an overdose), your doctor will check you for side effects.

If you forget your appointment to have TECVAYLI
It is very important to go to all your appointments. If you miss an appointment, make another one as soon as possible.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Very common (may affect more than 1 in 10 people):
- serious immune reaction ('cytokine release syndrome') that may cause fever, chills, nausea, headache, fast heart beat, feeling dizzy, and difficulty breathing
- low level of antibodies called 'immunoglobulins' in the blood (hypogammaglobulinaemia), which may make infections more likely
- low levels of a type of white blood cells (neutropenia)
- infection, which may include fever, chills, shivering, cough, shortness of breath, rapid breathing and rapid pulse

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
  - feeling less alert
  - having difficulty writing

Tell your doctor right away if you notice any of the above-listed serious side effects.

Other side effects
Other side effects are listed below. Tell your doctor or nurse if you get any of these side effects.

Very common (may affect more than 1 in 10 people):
- lung infection (pneumonia)
- COVID-19 infection caused by a virus called coronavirus (SARS-CoV-2)
- infected nose, sinuses or throat (upper respiratory tract infection)
- low levels of red blood cells (anaemia)
- low levels of blood platelets (cells that help blood to clot; thrombocytopaenia)
- 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
- decreased appetite
- feeling sick (nausea), diarrhoea, constipation, vomiting
- headache
- nerve damage that may cause tingling, numbness, pain or loss of pain sensation
- high blood pressure (hypertension)
- bleeding, which can be severe (haemorrhage)
- cough
- being short of breath (dyspnea)
- fever
- feeling very tired
- pain or muscle aches
- swollen hands, ankles or feet (oedema)
- skin reactions at or near the injection site, including redness of the skin, itching, swelling, pain, bruising, rash, bleeding

Common (may affect up to 1 in 10 people)
- severe infection throughout the body (sepsis)
- skin infection causing redness (cellulitis)
- low number of a type of white blood cell with a fever (febrile neutropenia)
- low levels of 'fibrinogen,' a type of protein in the blood, making it more difficult to form clots
- change in brain function (encephalopathy)
- low level of 'calcium' or 'sodium' in the blood (hypocalcaemia or hyponatremia)

- high level of ‘potassium’ in the blood (hyperkalemia)
- low level of ‘albumin’ in the blood (hypoalbuminaemia)
- low level of oxygen in the blood (hypoxia)
- increased level of ‘gamma-glutamyltransferase’ in the blood
- increased level of liver enzymes 'transaminases' in the blood
- increased level of ‘creatinine’ in the blood
- increased level of ‘amylase’ in the blood (hyperamylasemia)
- increased level of ‘lipase’ in the blood (hyperlipasaemia)
- blood tests may show it takes longer for blood to clot (INR increased and PTT prolongation)

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store TECVAYLI

TECVAYLI will be stored at the hospital or clinic by your doctor.

Keep this medicine out of the sight and reach of children.

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

Store in a refrigerator (2 °C - 8 °C). Do not freeze.

Store in the original carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Your healthcare professional will throw away any medicines that are no longer being used. These measures will help protect the environment.

6. Contents of the pack and other information

What TECVAYLI contains
- The active substance is teclistamab. TECVAYLI comes in two different strengths:
  - 10 mg/mL - one 3 mL vial contains 30 mg teclistamab
  - 90 mg/mL - one 1.7 mL vial contains 153 mg teclistamab

- The other ingredients are EDTA disodium salt dihydrate, glacial acetic acid, polysorbate 20, sodium acetate trihydrate, sucrose, water for injections (see “TECVAYLI contains sodium” in section 2).

Not all pack sizes and concentrations may be marketed

What TECVAYLI looks like and contents of the pack
TECVAYLI is a solution for injection (injection) and is a colourless to light yellow liquid.
TECVAYLI is supplied as a carton pack containing 1 glass vial.

Marketing Authorisation Holder
Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

Manufacturer
Patheon Manufacturing Services LLC
5900 Martin Luther King Jr. Hwy
Greenville
NC 27834
USA

To contact us, please visit our website www.janssen.com/contact-us

This leaflet was last revised in 14 October 2022

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists

The following information is intended for healthcare professionals only:

It is very important to that the instructions for preparation and administration provided in this section are strictly followed to minimise potential dosing errors with TECVAYLI 10 mg/mL and TECVAYLI 90 mg/mL vials.

TECVAYLI should be administered via subcutaneous injection only. Do not administer TECVAYLI intravenously.

TECVAYLI should be administered by a healthcare professional with adequately trained medical personnel and appropriate medical equipment to manage severe reactions, including cytokine release syndrome.

TECVAYLI 10 mg/mL and TECVAYLI 90 mg/mL vials are for single use only.

TECVAYLI vials of different strengths should not be combined to achieve maintenance dose.

Aseptic technique should be used to prepare and administer TECVAYLI.

Any unused medicinal product or waste material should be disposed in accordance with local requirements.

Preparation of TECVAYLI

- Verify the prescribed dose for each TECVAYLI injection. To minimise errors, use the following tables to prepare TECVAYLI injection.
    - Use Table 1 to determine total dose, injection volume and number of vials required based on patient's actual body weight for Step-up dose 1 using TECVAYLI 10 mg/mL vial.

Table 1: Injection volumes of TECVAYLI (10 mg/mL) for Step-up dose 1 (0.06 mg/kg)

	Body weight (kg)	Total dose (mg)	Volume of injection (mL)	Number of vials (1 vial=3 mL)
Step-Up dose 1 (0.06 mg/kg)	35-39	2.2	0.22	1
	40-44	2.5	0.25	1
	45-49	2.8	0.28	1
	50-59	3.3	0.33	1
	60-69	3.9	0.39	1
	70-79	4.5	0.45	1
	80-89	5.1	0.51	1
	90-99	5.7	0.57	1
	100-109	6.3	0.63	1
	110-119	6.9	0.69	1
	120-129	7.5	0.75	1
	130-139	8.1	0.81	1
	140-149	8.7	0.87	1
	150-160	9.3	0.93	1

    - Use Table 2 to determine total dose, injection volume and number of vials required based on patient's actual body weight for Step-up dose 2 using TECVAYLI 10 mg/mL vial.

Table 2: Injection volumes of TECVAYLI (10 mg/mL) for Step-up dose 2 (0.3 mg/kg)

	Body weight (kg)	Total dose (mg)	Volume of injection (mL)	Number of vials (1 vial=3 mL)
Step-up dose 2 (0.3 mg/kg)	35-39	11	1.1	1
	40-44	13	1.3	1
	45-49	14	1.4	1
	50-59	16	1.6	1
	60-69	19	1.9	1
	70-79	22	2.2	1
	80-89	25	2.5	1
	90-99	28	2.8	1
	100-109	31	3.1	2
	110-119	34	3.4	2
	120-129	37	3.7	2
	130-139	40	4.0	2
	140-149	43	4.3	2
	150-160	47	4.7	2

    - Use Table 3 to determine total dose, injection volume and number of vials required based on patient's actual body weight for the maintenance dose using TECVAYLI 90 mg/mL vial.

Table 3: Injection volumes of TECVAYLI (90 mg/mL) for maintenance dose (1.5 mg/kg)

	Body weight (kg)	Total dose (mg)	Volume of injection (mL)	Number of vials (1 vial=1.7 mL)
Maintenance dose (1.5 mg/kg)	35-39	56	0.62	1
	40-44	63	0.70	1
	45-49	70	0.78	1
	50-59	82	0.91	1
	60-69	99	1.1	1

	70-79	108	1.2	1
	80-89	126	1.4	1
	90-99	144	1.6	1
	100-109	153	1.7	1
	110-119	171	1.9	2
	120-129	189	2.1	2
	130-139	198	2.2	2
	140-149	216	2.4	2
	150-160	234	2.6	2

- Remove the appropriate strength TECVAYLI vial from refrigerated storage (2 °C–8 °C) and equilibrate to ambient temperature (15 °C – 30 °C), as needed, for at least 15 minutes. Do not warm TECVAYLI in any other way.
- Once equilibrated, gently swirl the vial for approximately 10 seconds to mix. Do not shake.
- Withdraw the required injection volume of TECVAYLI from the vial(s) into an appropriately sized syringe using a transfer needle.
    - Each injection volume should not exceed 2.0 mL. Divide doses requiring greater than 2.0 mL equally into multiple syringes.
- TECVAYLI is compatible with stainless steel needles, polypropylene and polycarbonate syringe material.
- Replace the transfer needle with an appropriately sized needle for injection.
- Visually inspect TECVAYLI for particulate matter and discolouration prior to administration. Do not use if the solution is discoloured, or cloudy, or if foreign particles are present.
    - TECVAYLI solution for injection is colourless to light yellow.

Administration of TECVAYLI

- Inject the required volume of TECVAYLI into the subcutaneous tissue of the abdomen (preferred injection site). Alternatively, TECVAYLI may be injected into the subcutaneous tissue of the thigh. If multiple injections are required, TECVAYLI injections should be at least 2 cm apart.
- Do not inject into tattoos or scars or areas where the skin is red, bruised, tender, hard or not intact.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.