PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Tecvayli® 10 mg/ml

Tecvayli® 90 mg/ml

Solution for injection

Active ingredient

The active ingredient is teclistamab.

- Tecvayli 10 mg/ml – 3 ml vial containing 30 mg teclistamab
- Tecvayli 90 mg/ml – 1.7 ml vial containing 153 mg teclistamab

Inactive and allergenic ingredients in the preparation: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

In addition to the leaflet, Tecvayli has a Patient Safety Information Card.
This card contains important safety information that you must know and adhere to before starting and during treatment with Tecvayli. Read the Patient Safety Information Card and the patient leaflet before starting to use the preparation. Keep the card for further reading, if necessary.

1. WHAT IS THE MEDICINE INTENDED FOR?

Tecvayli is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

Therapeutic group: Other monoclonal antibodies and antibody drug conjugates, L01FX24.

How does Tecvayli work?

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

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

you are sensitive (allergic) to the active ingredient, or any of the additional ingredients contained in the medicine (see section 6).

If you are not sure if you are sensitive (allergic), speak to your doctor or nurse before taking Tecvayli.

Special warnings regarding use of the medicine

Before treatment with Tecvayli, inform the doctor if:

- you had a stroke or seizure within the past 6 months.
- you 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 doctor will check you for signs of hepatitis B before, during and for some time after treatment with Tecvayli. Tell your doctor or nurse if you get worsening tiredness, or yellowing of your skin or white part of your eyes.

At any time during or after your treatment, tell your doctor or nurse immediately if:

- you 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 vision, loss of vision 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.

Tecvayli and vaccines

Before treatment with Tecvayli, tell your doctor or nurse if you recently received a vaccination or are going to receive a vaccination.

You should not receive live vaccinations starting from 4 weeks before to 4 weeks after treatment with Tecvayli.

Look out for serious side effects.

Tell your doctor or nurse straight away if you experience any of the following effects:

- Signs of a disturbance known as “cytokine release syndrome” (CRS). CRS is a serious immune reaction, with symptoms such as fever, chills, nausea, headache, fast heart rate, feeling dizzy and difficulty breathing.
- Effects on the nervous system. Symptoms include feeling confused, feeling less alert, sleepy, or having difficulty writing and/or speaking. Some of these symptoms 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 of the above signs.

Children and adolescents
Do not give Tecvayli to children or adolescents under 18 years of age.

Tests and follow-up
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 to receive Tecvayli. Your doctor will also check if you are pregnant or breastfeeding.

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.

Drug interactions
If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.

Pregnancy and breastfeeding
It is not known if Tecvayli affects the unborn baby or passes into breast milk.

Information for women about pregnancy
If you are pregnant, think you might be pregnant or are planning to have a baby, tell your doctor or nurse before receiving Tecvayli.
If you become pregnant while being treated with this medicine, tell your doctor or nurse straight away. Tecvayli is associated with hypogammaglobulinaemia; therefore, consider evaluation of immunoglobulin levels in newborns of mothers who were treated with Tecvayli.

Information for men about pregnancy
If your partner becomes pregnant while you are being treated with this medicine, tell your doctor straight away.

Contraception – information for women who could become pregnant
If you could become pregnant, you must use effective contraception during treatment and for 5 months after stopping treatment with Tecvayli.

Contraception – information for men (who are taking Tecvayli)
If your partner could become pregnant, you must use effective contraception during treatment and for 3 months after stopping treatment with Tecvayli.

Breastfeeding
It is not known if Tecvayli passes into breast milk. Do not breastfeed during the course of treatment with Tecvayli. If a decision was made to stop treatment with Tecvayli, you should not breastfeed for 5 months after stopping treatment.

Driving and using machinery
The medicine has a significant effect on ability to drive and operate machinery. Some people may feel tired, dizzy or confused while taking Tecvayli. Do not drive, use tools, operate heavy machinery, or do things that can endanger you until at least 48 hours after receiving your third dose of Tecvayli, or as instructed by your doctor.

Important information about some of the ingredients of the medicine

Sodium

Tecvayli contains less than 1 mmol (23 mg) sodium per dose, that is to say it is essentially “sodium-free”.

Polysorbate

Tecvayli contains 0.4 mg of polysorbate 20 in each ml, which is equivalent to 1.2 mg per 3 ml vial and 0.68 mg per 1.7 ml vial. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor’s instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only. The dosage will depend on body weight. The first two doses will be lower.
Tecvayli is administered as follows:

- For the first dose, you will receive 0.06 mg per kg bodyweight.
- For the second dose 2-7 days later, you will receive 0.3 mg per kg body weight.
- You will then receive a maintenance dose of 1.5 mg per kg body weight 2-7 days after the second dose.
- You will then continue receiving a maintenance dose once a week, for as long as you are benefiting from Tecvayli.

If you are continuing to receive benefit from Tecvayli after 6 months, your doctor may decide that you will receive a maintenance dose every two weeks.

Do not exceed the recommended dose.

Your doctor will monitor you for side effects after each of your first three doses. He will do this for two days after each dose.

If you suffer from side effects, stay close to a healthcare facility after the first three doses.

How the medicine is given

Tecvayli will be given to you by a doctor or nurse as an injection under the skin (subcutaneous injection). The injection is given in the stomach area or thigh.

Other medicines given during treatment with Tecvayli

You will be given medicines 1-3 hours before each of the first three doses of Tecvayli, which will help to lower the chance of side effects, such as CRS. 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 before later doses, based on the symptoms you experience.
You may also be given additional medicines based on the symptoms you experience or your medical history.

If you received an overdose (a higher amount than needed) of Tecvayli
This medicine will be given by your doctor or nurse; it is unlikely that you will receive too much.
In the event that you received more than required (an overdose), your doctor will check you for side effects.
If you forget the appointment to receive Tecvayli
It is very important to go to all appointments. If you missed an appointment, schedule another one as soon as possible.
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Tecvayli may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Serious side effects
Seek medical assistance straight away if you develop any of the following serious side effects, which may be severe and fatal.

Very common side effects – effects that occur in more than one user in ten:
- serious immune reaction ("cytokine release syndrome") that may cause fever, chills, nausea, headache, fast heart rate, feeling dizzy and difficulty breathing
- low level of antibodies called immunoglobulins in the blood (hypogammaglobulinaemia), an effect which may make infections more likely
- low levels of a certain type of white blood cells (neutropenia)
- infection, which may include fever, chills, shivering, cough, shortness of breath, rapid breathing and rapid pulse

Common side effects – effects that occur in up to one user in ten:
- effects on the nervous system. These may be signs of a serious and potentially fatal immune reaction called "immune effector cell-associated neurotoxicity syndrome" (ICANS). Some of the symptoms are:
  - feeling confused
  - feeling less alert
  - difficulty writing
  - difficulty speaking
  - sleepiness
  - loss of ability to carry out skilled movement and gestures (despite having the physical ability and desire to perform them)

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

Uncommon side effects – may affect up to 1 in 100 users:

- a serious and potentially fatal brain infection called Progressive Multifocal Leukoencephalopathy (PML). Some of the symptoms are:
  - blurred vision, loss of vision 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

Additional side effects

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

Very common side effects – effects that occur in more than one user in ten:

- pain
- lung infection (pneumonia)
- COVID-19 infection caused by a coronavirus (SARS-CoV-2)
- infection of the nose, sinuses or throat (upper respiratory tract infection)
- urinary tract infection
- low levels of red blood cells (anemia)
- low levels of blood platelets (cells that help blood to clot; thrombocytopenia)
- low number of white blood cells (leukopenia)
- low levels of a certain type of white blood cells (lymphopenia)
- low level of phosphate, magnesium or potassium in the blood (hypophosphatemia, hypomagnesemia or hypokalemia)
- increased level of calcium in the blood (hypercalcaemia)
- increased level of alkaline phosphatase in the blood
- decreased appetite
- nausea, diarrhea, constipation, vomiting, abdominal pain
- headache
- nerve damage that may cause tingling, numbness, pain or loss of pain sensation
- muscle spasms
- high blood pressure (hypertension)
- bleeding, which can be severe
- hypotension
- cough
- shortness of breath (dyspnea)
- fever
- feeling very tired
- pain or muscle aches. Pain in musculoskeletal system.
- swelling of the 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 side effects – effects that occur in up to one user in ten:

- severe infection throughout the body (sepsis)
- skin infection causing redness (cellulitis)
- low number of a certain 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 (hypoalbuminemia)
- low level of sugar in the blood (hypoglycaemia)
- low level of oxygen in the blood (hypoxia)
- increased level of gamma-glutamyltransferase in the blood
- increased level of liver enzymes (transaminase enzymes) 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 (hyperlipasemia)
- blood tests may show it takes longer for blood to clot (INR increased and PTT prolongation)

If a side effect occurs, if one of the side effects worsens, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects or by entering the link:

https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package/label. The expiry date refers to the last day of that month.

Storage conditions:

Tecvayli will be stored in the hospital or by the doctor in the clinic.

Store in a refrigerator (2°C-8°C). Do not freeze. Store in the original package to protect from light.

Do not discard the medicine via wastewater or household waste. The medical staff will throw away the medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Sucrose, sodium acetate trihydrate, polysorbate 20, glacial acetic acid, EDTA disodium salt dihydrate, water for injections.

What the medicine looks like and contents of the pack:

Solution for injection, colorless to light yellow liquid.

Tecvayli is provided in a package that contains one glass vial.

Registration Holder: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Manufacturer: Janssen Biologics B.V. Einsteinweg 101 2333 CB Leiden, The Netherlands

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Tecvayli 10 mg/ml: 173 74 37566 00

Tecvayli 90 mg/ml: 173 75 37567 00

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