MEDICATION GUIDE
TECVAYLI® [tek vay' lee]
(teclistamab-cqyv) injection, for subcutaneous use

What is the most important information I should know about TECVAYLI?

TECVAYLI may cause side effects that are serious, life-threatening or lead to death, including Cytokine Release Syndrome (CRS) and Neurologic problems.

Call your healthcare provider right away if you develop any of the signs or symptoms of CRS or neurologic problems listed below at any time during your treatment with TECVAYLI:

Cytokine Release Syndrome (CRS). Signs and symptoms of CRS may include:

- fever (100.4 °F or higher)
- difficulty breathing
- chills
- dizziness or lightheadedness
- fast heartbeat
- feeling anxious
- confusion or restlessness
- headache
- increased liver enzymes in your blood

Neurologic problems. Symptoms of neurologic problems with TECVAYLI include:

- headache
- jerking movements
- rigid muscles
- feeling restless
- numbness and tingling (feeling like "pins and needles")
- confusion
- trouble speaking
- muscle spasms
- tremor
- double vision
- changes in your handwriting
- problems walking
- muscle weakness in your body or face
- hearing loss
- burning, throbbing, or stabbing pain

- Due to the risk of CRS and neurologic symptoms, you should be hospitalized for 48 hours after all doses of TECVAYLI that are part of the "step-up dosing schedule." The "step-up dosing schedule" is when you receive the first 2 doses of TECVAYLI, which are called "step-up" doses, and then you receive the first "treatment dose" of TECVAYLI. After "step-up" dose 1 of TECVAYLI, the dose of TECVAYLI is increased. After "step-up" dose 2, the dose is increased again when you receive the first "treatment dose" of TECVAYLI.
  - "Step-up dose 1" is given on day 1 of treatment. "Step-up dose 2" is usually given on day 4 of treatment. The first "treatment dose" is usually given on day 7 of treatment.
  - Your healthcare provider will decide when you will receive "step-up dose 2" and your first "treatment dose."
    - "Step-up" dose 2 may be given between 2 to 4 days after "step-up" dose 1, or up to 7 days after "step-up" dose 1 if you have certain side effects with TECVAYLI.
    - Your first "treatment dose" may be given between 2 to 4 days after "step-up" dose 2, or up to 7 days after "step-up" dose 2 if you have certain side effects with TECVAYLI.
  - Your healthcare provider will decide the number of days to wait between your doses of TECVAYLI as well as how many treatments you will receive.
  - If your dose of TECVAYLI is delayed for any reason, you may need to repeat the "step-up dosing schedule" to receive TECVAYLI.
  - Before each "step-up" dose and your first "treatment dose" of TECVAYLI you will receive medicines to help reduce your risk of CRS. Your healthcare provider will decide if you need to receive medicines to help reduce your risk of CRS with future doses.
- Your healthcare provider will monitor you for signs and symptoms of CRS and neurologic problems during treatment with TECVAYLI, as well as other side effects and treat you as needed.
- **Do not drive or operate heavy or dangerous machinery during and for 48 hours after your TECVAYLI "step-up dosing schedule" is completed, or at any time during treatment with TECVAYLI if you develop new neurologic symptoms until the symptoms go away.**

TECVAYLI is available only through the TECVAYLI and TALVEY Risk Evaluation and Mitigation Strategy (REMS) due to the risk of CRS and neurologic problems.

You will receive a Patient Wallet Card from your healthcare provider. **Carry the Patient Wallet Card with you at all times and show it to all of your healthcare providers.** The Patient Wallet Card lists signs and symptoms of CRS and neurologic problems.

Get medical help right away if you develop any of the signs and symptoms listed on the Patient Wallet Card. You may need to be treated in a hospital.

- If you have any questions about TECVAYLI, ask your healthcare provider.
- Your healthcare provider may temporarily stop or completely stop your treatment with TECVAYLI if you develop CRS, neurologic problems or any other side effects that are severe.

See **"What are the possible side effects of TECVAYLI?"** for more information about side effects.

What is TECVAYLI?

TECVAYLI is a prescription medicine to treat adults with multiple myeloma who:

- have already received at least 4 treatment regimens, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody to treat their multiple myeloma,
  and
- their cancer has come back or did not respond to prior treatment

It is not known if TECVAYLI is safe and effective in children.

Before you receive TECVAYLI, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- are pregnant or plan to become pregnant. TECVAYLI may harm your unborn baby.
  - Your healthcare provider should do a pregnancy test before you start treatment with TECVAYLI.
  - You should use effective birth control (contraception) during treatment and for 5 months after your last dose of TECVAYLI.
  - Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with TECVAYLI.
- are breastfeeding or plan to breastfeed. It is not known if TECVAYLI passes into your breast milk. Do not breastfeed during treatment and for 5 months after your last dose of TECVAYLI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive TECVAYLI?

- TECVAYLI will be given to you by your healthcare provider as an injection under your skin (subcutaneous injection), usually in your stomach-area (abdomen), your thigh or another area of your body may be injected.
- **See "What is the most important information I should know" at the beginning of this Medication Guide for information about how you will receive TECVAYLI.**
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment. It is important for you to be monitored closely for side effects during treatment with TECVAYLI.

What are the possible side effects of TECVAYLI?

TECVAYLI may cause serious side effects, including:

- See **"What is the most important information I should know about TECVAYLI?"**
- **Liver problems.** TECVAYLI can cause liver problems that may lead to death. Increased bilirubin and liver enzymes in your blood are common with TECVAYLI and can also sometimes be severe These increases in liver enzymes can happen with or without you also having CRS. Your healthcare provider will monitor you for these problems before you start and during treatment with TECVAYLI. **Tell your healthcare provider if you develop any symptoms of a liver problem including:**
  - tiredness
  - loss of appetite
  - pain in your right upper stomach-area (abdomen)
  - dark urine
  - yellowing of your skin or white part of your eyes
- **Infections.** Upper respiratory tract infections and pneumonia are common with TECVAYLI. TECVAYLI can cause bacterial and viral infections that are severe, life-threatening, or that may lead to death.
  - Your healthcare provider will monitor you for signs and symptoms of infection before and during treatment with TECVAYLI.
  - Your healthcare provider may prescribe medicines for you to help prevent infections and treat you as needed if you develop an infection during treatment with TECVAYLI.
  - Tell your healthcare provider right away if you get a fever, chills or any signs or symptoms of an infection.
- **Decreased white blood cell counts.** Decreased white blood cell counts are common with TECVAYLI and can also be severe. Fever sometimes also happens with low white blood cell counts and may be a sign that you have an infection. Your healthcare provider will check your blood cell counts before you start and during treatment with TECVAYLI, and treat you as needed.
- **Allergic reactions and injection site reactions.** TECVAYLI can cause allergic reactions that can affect your whole body (systemic), and also cause injection site reactions.
  - Some people taking TECVAYLI can develop symptoms of an allergic reaction that can affect your whole body and may include fever or a swollen tongue. **Get medical help right away if you develop symptoms of an allergic reaction during treatment with TECVAYLI.**
  - Injection site reactions are common with TECVAYLI and can include: redness, heat, swelling, bruising, bacterial skin infection (cellulitis), discomfort, blood collection under the skin at the injection site (hematoma), and rash. Tell your healthcare provider if you develop any severe injection site reactions.

Your healthcare provider may temporarily or permanently stop TECVAYLI if you have any of the side effects listed above and they are severe.

The most common side effects of TECVAYLI include:

- fever
- pain in your joints and muscles, back and chest muscles, and in your arms and legs
- tiredness and weakness
- upper respiratory tract infections and pneumonia. See "Infections" above.
- nausea
- headache
- diarrhea

The most common severe abnormal lab test results with TECVAYLI include: decreased white blood cells, red blood cells and platelets.

These are not all the possible side effects of TECVAYLI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General Information about TECVAYLI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

You can ask your healthcare provider for information about TECVAYLI that is written for health professionals.

What are the ingredients of TECVAYLI?

Active ingredient: teclistamab-cqyv

Inactive ingredients: edetate disodium, glacial acetic acid, polysorbate 20, sodium acetate, sucrose, Water for Injection

Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, USA
U.S. License Number 1864
For patent information: www.janssenpatents.com

For more information about TECVAYLI go to www.TECVAYLI.com or call 1-800-526-7736.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: Aug 2025

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