

MEDICATION GUIDE

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

TECVAYLI[®] can cause side effects that are serious, life-threatening or cause death, including cytokine release syndrome (CRS) and neurologic problems.

- **Cytokine Release Syndrome (CRS).** Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of CRS, including:
 - 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. See **“What are the possible side effects of TECVAYLI[®]?”** for information about the signs and symptoms of liver problems.

Due to the risk of CRS, you will receive TECVAYLI[®] on a “step-up dosing” schedule. You should be hospitalized for 48 hours after the first and second step-up doses and should stay close to a healthcare facility and be monitored by a healthcare provider for 48 hours after you receive your first treatment dose.

- During the step-up dosing schedule your TECVAYLI[®] dose will be increased for the first 3 doses. You will receive:
 - a smaller step-up dose as your first dose on day 1 of treatment
 - an increased step-up dose as your second dose, usually around day 3 or 4 of treatment
 - an increased dose as your first treatment dose, usually around day 7 of treatment
- Your healthcare provider will decide the number of days to wait between your doses of TECVAYLI[®] and 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.
- 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 with future doses.

What is the most important information I should know about TECVAYLI[®]? (cont'd)

- **Neurologic problems.** Tell your healthcare provider or get medical help right away if you develop any signs and symptoms of neurologic problems, including:
 - headache
 - jerking movements
 - rigid muscles
 - feeling restless
 - numbness and tingling (feeling like “pins and needles”)
 - feeling less alert
 - feeling disorientated, confused, or seeing or hearing things that are not real (hallucinations)
 - trouble speaking
 - muscle spasms
 - tremor
 - double vision
 - changes in your handwriting
 - problems walking
 - muscle weakness in your body or face
 - burning, throbbing, or stabbing pain
 - feeling sleepy
 - memory problems

Your healthcare provider will monitor you for signs and symptoms of CRS and neurologic problems during treatment with TECVAYLI[®] and treat you as needed. Your healthcare provider may temporarily stop or completely stop your treatment with TECVAYLI[®] if you develop CRS or neurologic problems.

- **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.

See **“What are the possible side effects of TECVAYLI[®]?”** for more information about side effects.

What is TECVAYLI[®]?

TECVAYLI[®] is a prescription medicine used to treat adults with multiple myeloma that has come back or did not respond to prior treatment:

- in combination with daratumumab and hyaluronidase-fihj in people who have received at least 1 treatment regimen, including a proteasome inhibitor and an immunomodulatory agent.
- alone in people who have received at least 4 treatment regimens, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

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[®].
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What should I avoid while receiving TECVAYLI[®]?

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 such as dizziness, confusion, tremors, sleepiness, or any other symptoms that impair your consciousness, until the symptoms go away. See **“What is the most important information I should know about TECVAYLI[®]?”** for more information about signs and symptoms of neurologic problems.

What are the possible side effects of TECVAYLI[®]?

TECVAYLI[®] can 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 cause death. Increases in liver enzymes can happen with or without CRS. **Tell your healthcare provider right away 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

What are the possible side effects of TECVAYLI[®]? (cont'd)

- **Infections.** TECVAYLI[®] can cause bacterial and viral infections that are severe, life-threatening, or that may cause death.
 - 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.** Fever sometimes also happens with low white blood cell counts and may be a sign that you have an infection. Your healthcare provider will treat you as needed.
- **Allergic reactions and injection site reactions.**
 - **Allergic reactions:** can include fever, rash, swollen tongue, or trouble breathing. **Get medical help right away if you develop any symptoms of an allergic reaction during treatment with TECVAYLI[®].**
 - **Injection site reactions:** 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.

What are the possible side effects of TECVAYLI[®]? (cont'd)

Your healthcare provider will check your liver enzymes and white blood cell counts before you start and during treatment with TECVAYLI[®].

Your healthcare provider will monitor you for signs and symptoms of these serious side effects during treatment and may temporarily or permanently stop TECVAYLI[®] if you develop severe side effects.

The most common side effects of TECVAYLI[®] when used alone include:

- fever
- CRS
- muscle, joint, and bone pain
- injection site reaction
- tiredness
- upper respiratory tract infection
- nausea
- headache
- pneumonia
- diarrhea

The most common side effects of TECVAYLI[®] when used with daratumumab and hyaluronidase-fihj include:

- low blood levels of antibodies called immunoglobulins
- upper respiratory tract infection
- CRS
- cough
- diarrhea
- muscle, joint, and bone pain
- COVID-19
- pneumonia
- injection site reaction
- tiredness
- fever
- headache
- nausea
- stomach area pain or cramps
- decreased weight

What are the possible side effects of TECVAYLI[®]? (cont'd)

The most common severe abnormal blood 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 the safe and effective use of TECVAYLI[®]

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

You can ask your pharmacist or healthcare provider for information about TECVAYLI[®] that is written for health professionals.

What are the ingredients in 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

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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: Mar 2026