

MEDICATION GUIDE
TALVEY® [tal vay]
(talquetamab-tgvs) injection, for subcutaneous use

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

TALVEY 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 or get medical help 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 TALVEY:

Cytokine Release Syndrome (CRS). CRS is common during treatment with TALVEY and can also be serious, life-threatening, or lead to death. Signs and symptoms of CRS may include:

- fever (100.4°F or higher)
- dizziness or lightheadedness
- chills
- difficulty breathing
- feeling anxious
- headache
- fast heartbeat

Neurologic problems. Symptoms of neurologic problems with TALVEY may include:

- headache
 - feeling confused
 - being less alert or aware
 - feeling disoriented
 - trouble speaking or writing
 - shaking (tremors)
 - numbness and tingling (feeling like “pins and needles”)
 - problems with walking, or loss of balance or coordination
 - feeling sleepy
 - feeling very sleepy with low energy
 - slow or difficulty thinking
 - seizures
 - muscle weakness
 - memory loss
 - burning, throbbing, or stabbing pain
 - fast eye movements that you cannot control
- Due to the risk of CRS and neurologic problems, you should be hospitalized for 48 hours after all doses of TALVEY that are part of the “step-up dosing schedule”. The “step-up dosing schedule” is when you receive the first 2 or 3 doses of TALVEY, which are smaller “step-up” doses, and also the first full “treatment dose” of TALVEY.
 - TALVEY is given weekly or every 2 weeks. Your healthcare provider will decide the number of days to wait between your doses of TALVEY as well as how many treatments you will receive.
 - If you receive TALVEY weekly, “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.
 - If you receive TALVEY every 2 weeks, “Step-up dose 1” is given on day 1 of treatment. “Step-up dose 2” is usually given on day 4 of treatment. “Step-up dose 3” is usually given on day 7 of treatment. The first “treatment dose” is usually given on day 10 of treatment.
 - If your dose of TALVEY is delayed for any reason, you may need to repeat the “step-up dosing schedule” to receive TALVEY.
 - Before each “step up” dose of TALVEY, 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, neurologic problems, as well as other side effects and treat you as needed.

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

See **“What are the possible side effects of TALVEY?”** for more information about side effects.

What is TALVEY?

TALVEY is a prescription medicine used 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 TALVEY is safe and effective in children.

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

- have an infection
- are pregnant or plan to become pregnant. TALVEY may harm your unborn baby. Tell your healthcare provider if you become pregnant or think that you may be pregnant during treatment with TALVEY.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with TALVEY.
- You should use effective birth control (contraception) during treatment and for 3 months after your last dose of TALVEY.
- are breastfeeding or plan to breastfeed. It is not known if TALVEY passes into your breast milk. Do not breastfeed during treatment and for 3 months after your last dose of TALVEY.

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 TALVEY?

- TALVEY will be given to you by your healthcare provider as an injection under your skin (subcutaneous injection), usually in the stomach area (abdomen). TALVEY may also be injected into your thigh or another area of your body.
- **See “What is the most important information I should know about TALVEY?” at the beginning of this Medication Guide for information about how you will receive TALVEY.**
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

What should I avoid while receiving TALVEY?

Do not drive, operate heavy machinery, or do other dangerous activities during and for 48 hours after your TALVEY “step-up dose” is completed or at any time during treatment with TALVEY, if you develop dizziness, confusion, tremors, sleepiness, or any other symptoms of neurologic problems until your symptoms go away.

See **“What is the most important information I should know about TALVEY?”** for more information about signs and symptoms of CRS and neurologic problems.

What are the possible side effects of TALVEY?**TALVEY may cause serious side effects, including:**• **See “What is the most important information I should know about TALVEY?”**

- **Mouth problems and weight loss.** Tell your healthcare provider or get medical help right away if you develop any of the following symptoms of mouth problems:

- changes in sense of taste
- trouble swallowing
- dry mouth
- mouth sores

Your healthcare provider will monitor you for these symptoms and will monitor your weight during treatment with TALVEY. Tell your healthcare provider if you lose weight during treatment with TALVEY.

- **Infections.** TALVEY can cause serious infections that can be life-threatening and may lead to death. Your healthcare provider will monitor you for signs and symptoms of infection before and during treatment with TALVEY. Tell your healthcare provider right away if you get develop any signs or symptoms of infection during treatment with TALVEY, including:

- fever of 100.4°F (38°C) or higher
- shortness of breath
- chills
- painful rash
- cough
- sore throat
- chest pain
- pain during urination
- tiredness
- feeling weak or generally unwell

- **Decreased blood cell counts.** Decreased blood cell counts are common during treatment with TALVEY and can also be severe. Your healthcare provider will check your blood cell counts during treatment with TALVEY. Tell your healthcare provider if you get any symptoms of infection or unusual bleeding or bruising.

- **Skin problems.** Skin problems are common during treatment with TALVEY and can also be serious. Tell your healthcare provider if you get skin problems such as skin rash, raised red bumps, or redness of the skin.

- **Liver problems.** Abnormal liver tests can happen during treatment with TALVEY. Your healthcare provider will do blood tests before and during treatment with TALVEY to check your liver. Tell your healthcare provider if you develop any of the following symptoms of liver problems:

- tiredness
- dark urine
- loss of appetite
- yellowing of your skin or the white part of your eyes
- pain in your right upper stomach-area (abdomen)

The most common side effects of TALVEY include:

- fever
- changes in your sense of taste
- nail problems
- muscle or joint pain
- rash
- feeling very tired
- weight loss
- dry mouth
- very dry skin that may affect the mucous membranes (such as the mouth and eyes)
- difficulty swallowing
- infected nose, sinuses or throat (cold)
- diarrhea
- low blood pressure
- headache

The most common severe abnormal lab test results with TALVEY include: decreased white blood cells and red blood cells. These are not all the possible side effects of TALVEY.

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 TALVEY.

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 TALVEY that is written for health professionals.

What are the ingredients of TALVEY?

Active ingredient: talquetamab-tgvs

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

Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, USA

U.S. License Number 1864

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For patent information: www.janssenpatents.com

For more information, go to www.TALVEY.com or call 1-800-526-7736.