



TALVEYTM

(talquetamab-tgvs) Injection for
subcutaneous use

2 mg/mL and 40 mg/mL

WHAT YOU SHOULD KNOW ABOUT TALVEYTM

Please read full Prescribing Information,
including **Boxed WARNING**, for TALVEYTM.

About TALVEY™

What is TALVEY™ (talquetamab-tgvs)?

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.

TALVEY™ is approved based on patient response. Data are not yet available to show if TALVEY™ improves survival or symptoms.

It is not known if TALVEY™ is safe and effective in children.

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 or life-threatening. Signs and symptoms of CRS may include:

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

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

- headache
- numbness and tingling (feeling like “pins and needles”)
- slow or difficulty thinking
- feeling confused
- feeling sleepy
- seizures
- being less alert or aware
- feeling very sleepy with low energy
- muscle weakness
- feeling disoriented
- burning, throbbing, or stabbing pain
- trouble speaking or writing
- shaking (tremors)

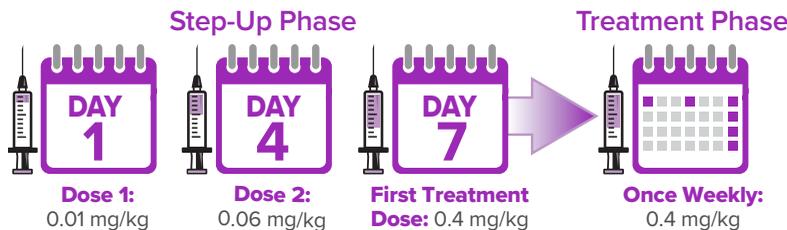
For more information go to [TALVEY.com](https://www.talvey.com) and sign up for updates

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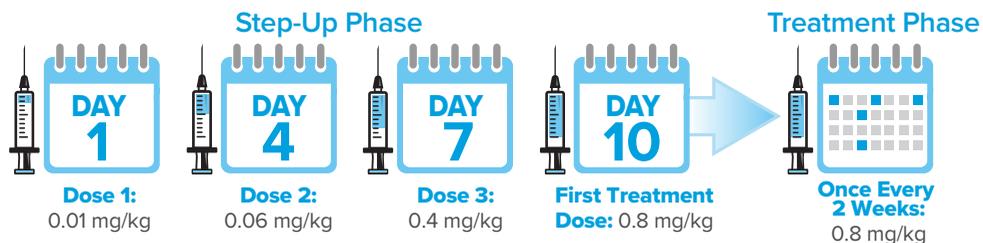
What is the most important information I should know about TALVEY™? (cont'd)

- 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.

ONCE-WEEKLY DOSING SCHEDULE



ONCE-EVERY-2-WEEKS DOSING SCHEDULE



Receiving TALVEY™

What is the most important information I should know about TALVEY™? (cont'd)

- 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™?”** later in the brochure for more information about side effects.

Please read full Prescribing Information, including Boxed WARNING, for TALVEY™.

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 final 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 final 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 brochure 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.

Potential side effects of TALVEY™



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 that impair consciousness until your signs and symptoms go away. These may be signs and symptoms of CRS or neurologic problems.

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
 - dry mouth
 - trouble swallowing
 - 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 or develop any signs or symptoms of infection during treatment with TALVEY™, including:
 - fever of 100.4°F (38°C) or higher
 - chills
 - cough
 - chest pain
 - tiredness
 - shortness of breath
 - painful rash
 - sore throat
 - pain during urination
 - feeling weak or generally unwell

Contact your healthcare provider right away if you think you are experiencing any side effects

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What are the possible side effects of TALVEY™? (cont'd)

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

The most common side effects of TALVEY™ include:

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



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.

***Ask your healthcare provider any questions
you have about TALVEY™***

Use the chart below to keep track of your doses

You can share this with your healthcare team at your follow-up appointments.

Name of doctor? _____

Facility where step-up dosing was received _____

Who to contact if I think I am experiencing a side effect? _____

Dose	Date and Time	Notes
Step-Up Dose 1		
Step-Up Dose 2		
For people taking a dose every 2 weeks Step-Up Dose 3		
Treatment Dose		

Please note: this is not intended to provide medical advice, diagnosis, treatment, or cure for any disease. This should not replace your individual treatment plan with your healthcare provider. You should always talk to your healthcare team about any scheduling, treatment, or dosing questions or concerns you may have.

To continue tracking your treatments, go to [TALVEY.com](https://www.talvey.com) to download and print additional copies

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Transitioning care

You may need to receive care at more than 1 healthcare facility as you start and continue treatment

You may receive care at different care centers while you are on TALVEY™, including inpatient or outpatient settings at a hospital or your healthcare provider's office.

Here are some tips to keep in mind during this transition of care:



Make sure to communicate and ask questions with your healthcare team while you are on treatment.



While undergoing the step-up phase, consider looking into where you will go for the treatment phase. If it will be at a new facility, consider scheduling your first appointment in advance.



To help you keep track of treatment, this brochure includes a section for you to jot down each time you're given a dose of medication.



It's also a good idea to keep track of how you're feeling each day so that you know if you're experiencing a side effect. This brochure also includes a tracker to record these details.



Ask if someone at your current treatment facility can help you review your insurance coverage to find out if there may be costs associated with your transition of care.



Remember to always carry your Patient Wallet Card wherever you go. Consider taking a picture of it with your cell phone as a backup.

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