

TALVEY® (talquetamab-tgvs)

What are the possible side effects of TALVEY?

Important information about TALVEY¹



- TALVEY may cause side effects that are serious, life-threatening or lead to death, including **cytokine release syndrome (CRS)** and **neurologic problems**.
- Due to the risk of these symptoms, TALVEY is only available through the **TECVAYLI** and **TALVEY Risk Evaluation and Mitigation Strategy (REMS)**.
 - You will be given a Patient Wallet Card from your healthcare provider that lists signs and symptoms of CRS and neurologic problems. Carry the Patient Wallet Card with you at all times and show it to all of your healthcare providers. You should call your healthcare provider or get medical help right away if you develop any of the signs or symptoms of CRS and neurologic problems listed below at any time during your treatment:



Cytokine release syndrome (CRS)¹

- Fever (100.4°F or higher)
- Fast heartbeat
- Chills
- Difficulty breathing
- Feeling anxious
- Headache
- Dizziness or lightheadedness



Neurologic problems¹

- 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

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Here is a passage from the TALVEY MEDICATION GUIDE, which may be helpful in addressing your question.¹



Please review the full TALVEY MEDICATION GUIDE for more information on “**What is the most important information I should know about TALVEY**” section.¹

What are the possible side effects of TALVEY?

TALVEY may cause serious side effects, including the following¹:

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

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 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

Decreased white 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.

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Skin problems¹



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 problems¹



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 white part of your eyes

The most common side effects of TALVEY include¹:



- 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 include¹:

- 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.¹
- You may report side effects to the Food and Drug Administration (FDA) at 1-800-FDA-1088.¹

This information is provided ONLY in response to your request and is not intended as medical advice, to promote the use of our product, or suggest using it in any manner other than as described in the PRESCRIBING INFORMATION. All decisions regarding your medical treatment should be made with your healthcare professional(s). Please contact your healthcare professional(s) to discuss the information in this response.

Please refer to the attached full PRESCRIBING INFORMATION and the PATIENT MEDICATION GUIDE for TALVEY.¹

1. TALVEY (talquetamab-tgvs) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc;

<https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/TALVEY-pi.pdf>.