


MY
JOURNEY
WITH
TALVEY®

See today with a different light

 **TALVEY**[®]
(talquetamab-tgvs) Injection for
subcutaneous use
2 mg/mL and 40 mg/mL

What is TALVEY[®] (talquetamab-tgvs)?

TALVEY[®] 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

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.

IMPORTANT SAFETY INFORMATION

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.

Please read full Important Safety Information on [pages 23-25](#). Please read full [Prescribing Information](#), including [Boxed Warning](#), and [Medication Guide](#) for TALVEY[®].

A guide to help you on your journey with TALVEY[®]

Welcome to your TALVEY® treatment journey

We're here to help you along the way

To help guide you through treatment with TALVEY®, this guidebook contains important information and helpful resources. Within it, you'll find tools, tips, trackers, and more—all designed to help you stay on track with treatment.

This guidebook should not replace the advice and guidance from your care team. If you have questions or would like more detailed information about your treatment, please talk to your healthcare provider.

Consider bringing this guidebook with you to appointments and referring to it throughout your treatment

YOU CAN USE THIS GUIDEBOOK TO:

- ✔ **TRACK** your progress through the treatment process
- ✔ **RECORD** your appointments and care team contact information
- ✔ **NOTE** how you're feeling or any symptoms you may experience
- ✔ **SHARE** your notes and questions with your care team throughout your journey

Please read full Important Safety Information on [pages 23-25](#). Please read full [Prescribing Information](#), including [Boxed Warning](#), and [Medication Guide](#) for TALVEY®.



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IMPORTANT SAFETY INFORMATION (cont'd)

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

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)
- 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”)
- feeling sleepy
- feeling very sleepy with low energy
- slow or difficulty thinking
- seizures
- muscle weakness
- memory loss
- burning, throbbing, or stabbing pain





TALVEY® OVERVIEW

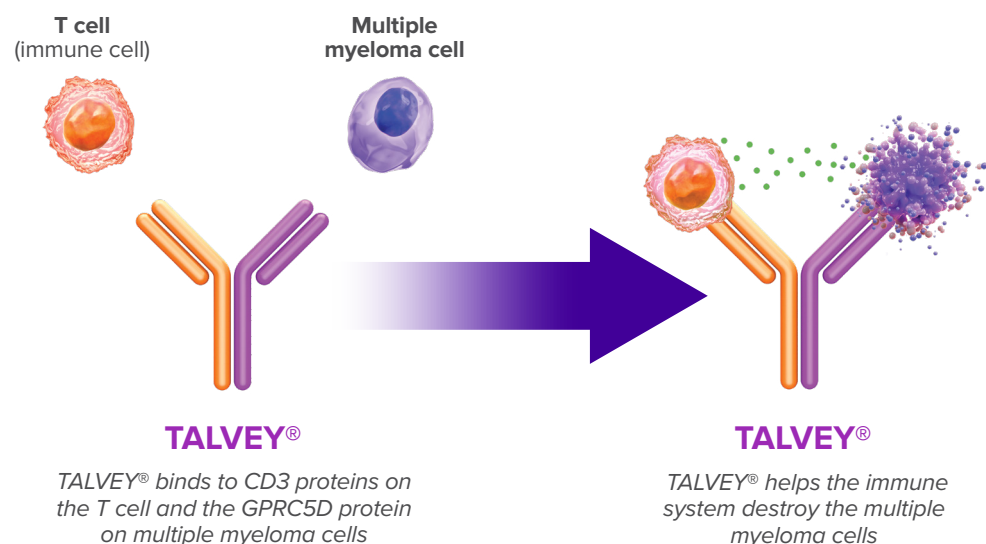
What is TALVEY®?

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. 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.

How TALVEY® works

- TALVEY® is a bispecific antibody that targets GPRC5D protein on the surface of multiple myeloma cells (as well as some healthy cells in the body) and CD3 proteins on T cells, a type of immune cell
- The binding of TALVEY® to both surface proteins may or can activate your immune system to help destroy the multiple myeloma cells in your body. This activation of your immune cells makes TALVEY® a type of immunotherapy

TALVEY® works with your body to help it recognize and destroy multiple myeloma cells



CD, cluster of differentiation; GPRC5D, G protein-coupled receptor class C group 5 member D.

TALVEY® is a ready-to-use treatment

TALVEY® is given as a subcutaneous injection. This means it will be given under the skin in the stomach area (abdomen), thigh, or another area of your body by a healthcare professional.

TALVEY® can be given once every two weeks or once weekly right from the start.

The treatment dose begins after the respective step-up dosing schedule. See page 8 for more details on dosing.



You may need to receive TALVEY® at a different treatment center from where you received your step-up doses. Talk to your healthcare provider if this may be the case for you.



Please see the **TALVEY® Patient Brochure** for more information.

IMPORTANT SAFETY INFORMATION (cont'd)

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.
- 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 and neurologic problems as well as other side effects, and treat you as needed.

TALVEY®
(talquetamab-tgvs) Injection for subcutaneous use
2 mg/mL and 40 mg/mL

Please read full Important Safety Information on pages 23-25. Please read full Prescribing Information, including Boxed Warning, and Medication Guide for TALVEY®.

TALVEY® OVERVIEW

Things to keep in mind as you start TALVEY®

Before starting TALVEY®, tell your healthcare provider 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 the last dose of TALVEY®



- Are taking specific medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements

Please read full Important Safety Information on [pages 23-25](#). Please read full [Prescribing Information](#), including [Boxed Warning](#), and [Medication Guide](#) for TALVEY®.



IMPORTANT SAFETY INFORMATION (cont'd)

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.

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®.





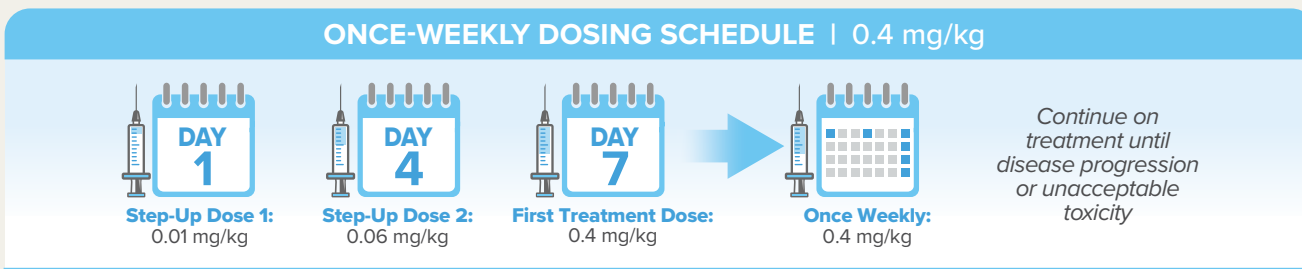
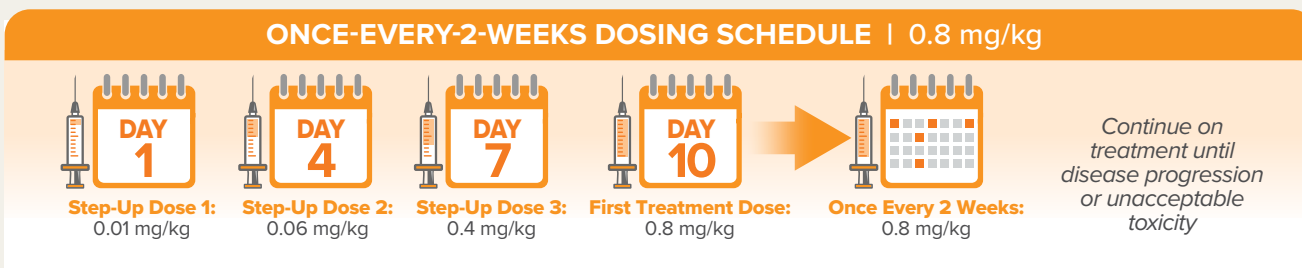
GETTING STARTED

TALVEY® starts with what is called a step-up dosing schedule

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® can be given once every 2 weeks or once weekly. Your healthcare provider will decide the number of days to wait between your doses of TALVEY®.

See the example schedule below.



Your healthcare team will decide which treatment schedule is best for you.

- 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, 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 as well as other side effects, and treat you as needed

Please read full Important Safety Information on pages 23-25. Please read full Prescribing Information, including Boxed Warning, and Medication Guide for TALVEY®.

Keeping track of your treatment

The chart below offers a space for you to record information about your treatment appointments and experiences during the step-up phase and beyond.

Share this chart with your care team at your appointments and work with them to fill it out:

Name of healthcare provider: _____

Phone number for healthcare provider: _____

Facility where step-up doses are received: _____

Facility where full treatment doses are received: _____

Who to contact in case of side effects: _____

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		
Treatment Dose		
Treatment Dose		
Treatment Dose		
Treatment Dose		
Treatment Dose		
Treatment Dose		
Treatment Dose		
Treatment Dose		
Treatment Dose		
Treatment Dose		
Treatment Dose		
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.

IMPORTANT SAFETY INFORMATION (cont'd)

Before you receive TALVEY®, tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

- **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 the 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.



GETTING STARTED

Once you and your doctor have decided that TALVEY® is right for you, Janssen has resources to help support your treatment journey

Personalized 1-on-1 Support

Starting and staying on track with a new medication can feel overwhelming. A Janssen Compass® Care Navigator is here to help with free personalized 1-on-1 support over the phone throughout your treatment journey.

Care partners can also participate and engage with a Care Navigator upon your request.

Connect with a Care Navigator today!

Call us at **844-628-1234**, Monday through Friday, 8:30 AM–8:30 PM ET.

Or sign up online to have a Care Navigator call them within 1 business day www.JanssenCompass.com/signup

You will talk to the same Care Navigator on every phone call. They will help you in 3 key areas:



Cost and Affordability:

Explore resources that may help you pay for your Janssen medication.



Medication and Disease Education:

Gain a better understanding of your disease and your Janssen medication. Learn tips for how to have meaningful conversations with loved ones and your care team during office visits.



Practical and Emotional Support:

Learn lifestyle and coping skills to help manage stress. Get connected to resources for your practical and emotional support needs, including support groups and transportation-related services.

Janssen Compass® is limited to education about your Janssen therapy, its administration, and/or your disease. It is intended to supplement your understanding of your therapy and is not intended to provide medical advice, replace a treatment plan from your doctor or nurse, or serve as a reason for you to start or stay on this medication.



Please read full Important Safety Information on [pages 23-25](#). Please read full [Prescribing Information](#), including [Boxed Warning](#), and [Medication Guide](#) for TALVEY®.

How to get ready for treatment day

Some tips to help you prepare for a new treatment.

On treatment days



Consider arranging transportation to and from appointments



As you prepare for your hospitalization, remember to pack an overnight bag with everything you might need during that time. Make plans with a care partner (including a family member or friend) to help take care of any children, pets, or plants



Wear comfortable clothing, as the injection site can be located on the stomach area (abdomen) or thigh

General tips



Ensure you have proper time to rest between treatments



Have a way to keep track of how you're feeling and communicate with your healthcare team about any side effects you may experience



Your healthcare provider will give you a TALVEY® Patient Wallet Card. This card includes important information about your TALVEY® treatment and lists the signs and symptoms of CRS and neurologic problems. You should carry the card with you at all times and show it to any healthcare provider involved in your care. This card is also available for download at www.tec-talrems.com/

IMPORTANT SAFETY INFORMATION (cont'd)

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®.



SIDE EFFECTS OF TALVEY®

Cytokine release syndrome (CRS) and neurologic problems

TALVEY® may cause side effects that are serious, life-threatening, or lead to death, including CRS and neurologic problems.

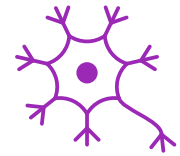
Call your healthcare provider right away if you develop any of the symptoms listed below at any time during your treatment with TALVEY®.

CRS is a condition that may occur after treatment with some types of immunotherapy, like TALVEY®. CRS is caused by a large, rapid release of cytokines into the blood from immune cells affected by the immunotherapy. Cytokines are immune substances that have different actions in your body. CRS is common during treatment with TALVEY® and can also be serious or life-threatening. Signs and symptoms 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”)
- feeling sleepy or very sleepy with low energy
- slow or difficulty thinking
- seizures
- muscle weakness
- memory loss
- burning, throbbing, or stabbing pain

- In order to reduce the risk of CRS and neurologic problems, you will have a step-up dosing schedule. The step-up dosing schedule is when you receive the first doses of TALVEY®, starting at a low dose and slowly increasing up to the full dose
- You should be hospitalized for 48 hours after all doses that are part of the step-up dosing schedule
 - More complete information regarding the dosing schedule can be found on [page 8](#)



Please read full Important Safety Information on [pages 23-25](#). Please read full [Prescribing Information](#), including [Boxed Warning](#), and [Medication Guide](#) for TALVEY®.

Using the ICE assessment tool

Your healthcare team may occasionally use something called the ICE assessment tool to see whether you're experiencing a certain neurological side effect. Your healthcare provider may provide additional guidance.

Preview of the ICE Assessment Tool



Orientation

Tell your healthcare provider what month and year it is, and which city and hospital you are in



Naming

Identify 3 objects that your healthcare provider points to



Following commands

Follow simple directions your healthcare provider gives you (for example, touch your nose)



Writing

Write down a sentence your healthcare provider tells you



Attention

Count backward from 100 by tens

ICE assessment tool, immune effector cell-associated encephalopathy assessment tool.

SIDE EFFECTS OF TALVEY®

What are the possible side effects of TALVEY®?

Talk to your healthcare provider right away if you develop any signs or symptoms of these side effects.



Mouth problems and weight loss

Signs and symptoms of mouth problems during treatment may include:

- 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

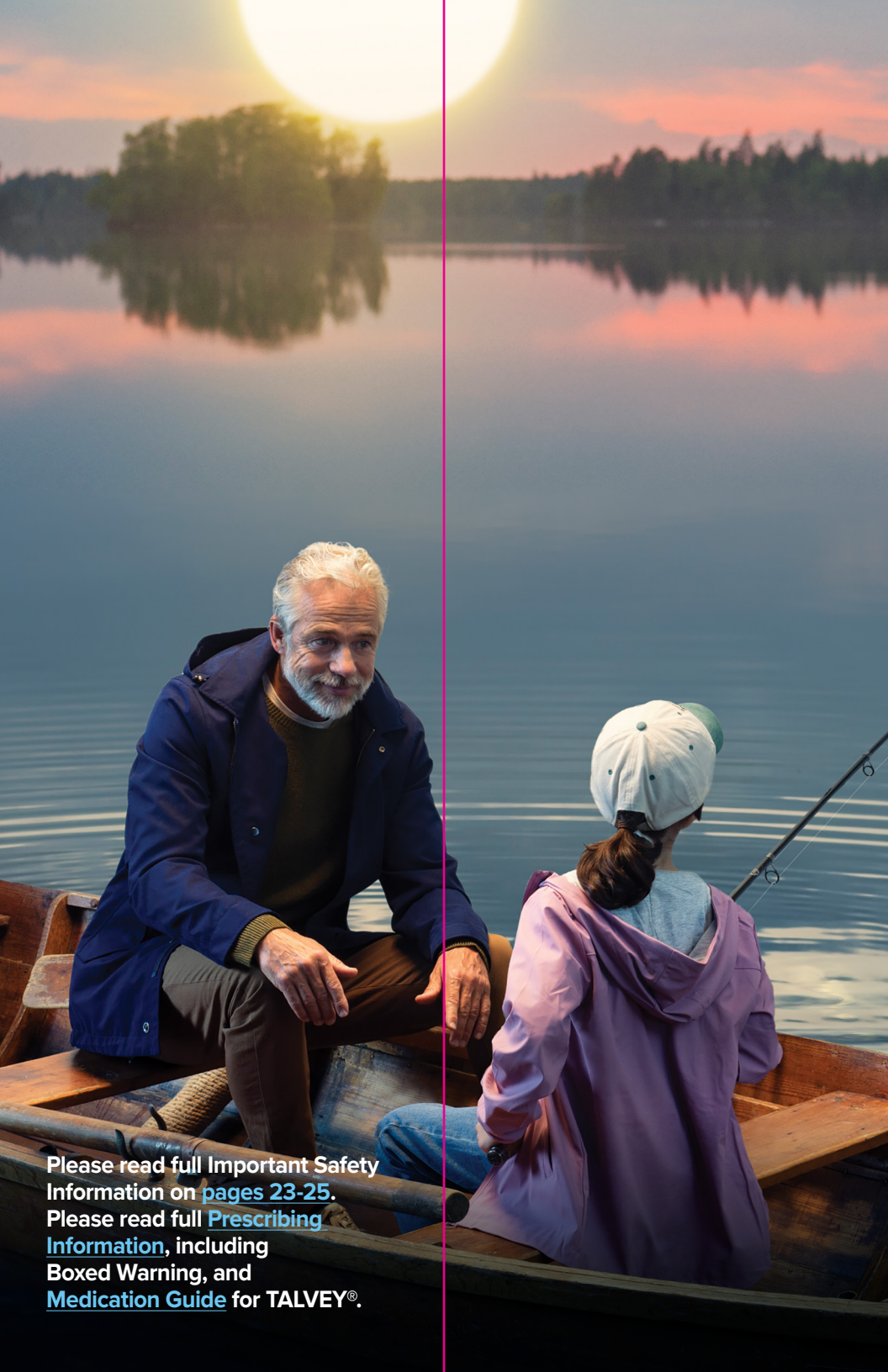


Decreased blood cell counts

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®.



Use the table on [pages 20-21](#) to keep track of how you're feeling each day and talk to your healthcare provider about it.



Please read full Important Safety Information on [pages 23-25](#). Please read full [Prescribing Information](#), including [Boxed Warning](#), and [Medication Guide](#) for 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
- Redness of the skin
- Very dry skin that may affect the mucous membranes (such as the mouth and eyes)



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



Problems with pregnancy


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®. Your healthcare provider should do a pregnancy test before you start treatment with TALVEY®. Females who are able to become pregnant on TALVEY® should use effective birth control (contraception) during treatment and for 3 months after the last dose of TALVEY®.



Most common side effects

- 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

These are not all the possible side effects of TALVEY®. Call your doctor for medical advice about side effects.

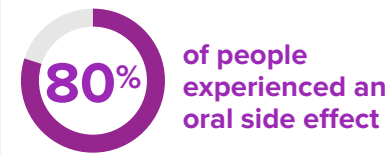
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SIDE EFFECTS OF TALVEY®

Occurrence of certain side effects seen in the clinical trial

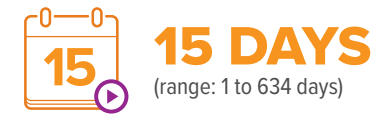
During the clinical trial, people experienced a variety of side effects at different times in their therapy. In some cases, side effects persisted throughout treatment. Your experience with side effects may differ from what is reported here.

Oral side effects



Median time to onset

The time it took for half of the people in the clinical trial to experience oral side effects was



Median time to resolution

The time it took for half of the peoples' oral side effects to resolve to baseline in the clinical trial was



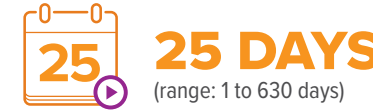
65% of people had oral side effects that did not resolve to baseline

Skin side effects



Median time to onset

The time it took for half of the people in the clinical trial to experience skin side effects was

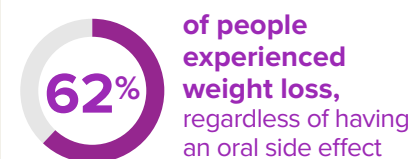


Median time to improvement

The time it took for half of the peoples' skin side effects to improve in the clinical trial was



Weight loss side effects



Median time to onset

The time it took for half of the people in the clinical trial to experience weight loss side effects was



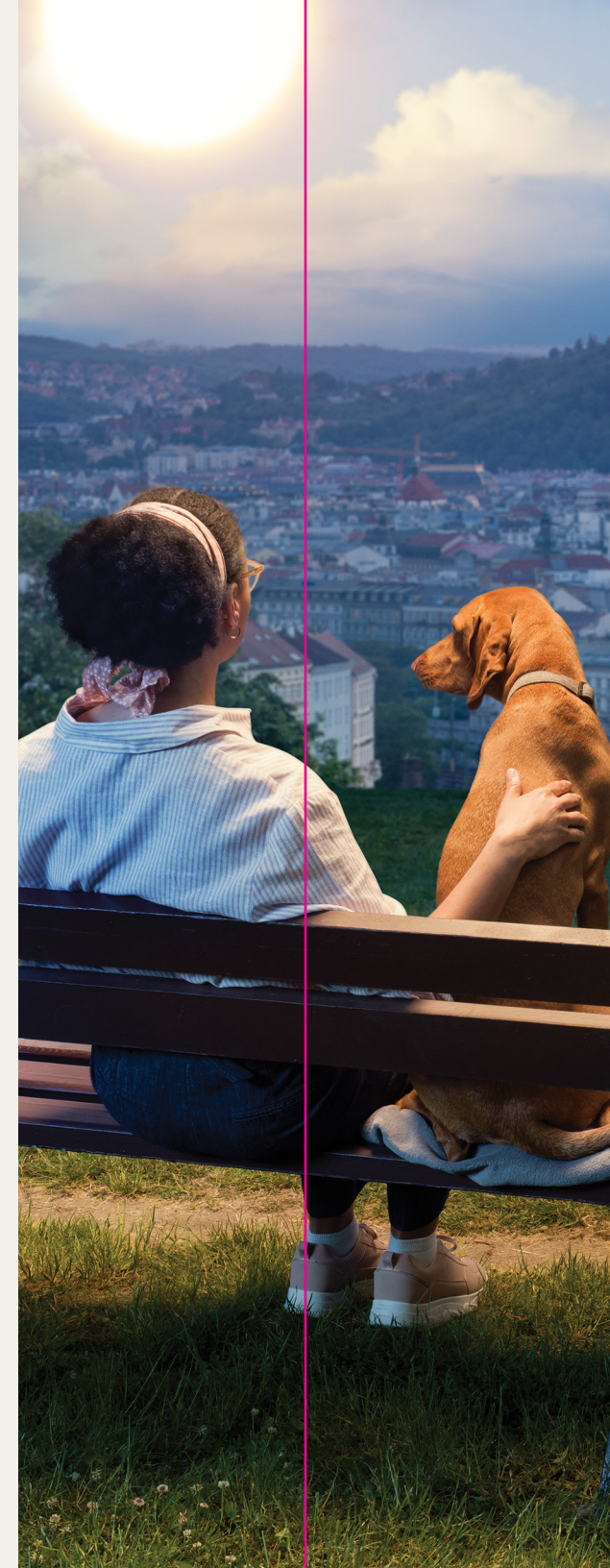
Median time to resolution

The time it took for half of the peoples' weight loss side effects to resolve in the clinical trial was



Weight loss did not resolve in 57% of people who reported it

Please read full Important Safety Information on [pages 23-25](#). Please read full [Prescribing Information](#), including Boxed Warning, and [Medication Guide](#) for TALVEY®.



Tips for coping with side effects

Please remember to talk to your healthcare team regularly about any side effects you are experiencing. These tips are just a few that may help you cope with some of your side effects. The tips below are not meant to replace talking to your healthcare team.

The recommendations below from The Leukemia & Lymphoma Society and the American Cancer Society may help people living with specific side effects. For more tips please see [lls.org](#) and [cancer.org](#).

Living with mouth problems



Maintain good dental hygiene



Keep your mouth moist with hard candy, drinking water, or other saliva substitutes



Avoid smoking

Living with weight loss



Maintain a food journal



Engage in physical activity



Maintain a nutritious diet

Living with skin changes



Take warm (not hot) baths or showers



Wash skin with mild soap and cleansers



Avoid direct sunlight and apply sunscreen



Pat skin dry



Use unscented lotion or moisturizing cream

Living with nail changes



Wear gloves when cleaning or gardening



Ask your doctor before you have a manicure



Avoid biting and picking on nails and cuticles



Keep fingernails and toenails neatly trimmed



Wear comfortable shoes with extra room around the toes

Your healthcare provider will weigh you during treatment and may consult a nutritionist.

For more information from lls.org

[Dental and Oral Complications of Cancer Treatment](#)

[Healthy Lifestyle Habits for a Better Quality of Life](#)

[Managing Low Appetite and Weight Loss](#)

[Caring for Skin, Nails, Hair, and Mouth](#)





SIDE EFFECTS OF TALVEY®

Keeping track of how you're feeling throughout your TALVEY® treatment journey

Date	How are you feeling?	Notes
03/29/24	Tired	Started after lunch and lasted 2 hours

Please read full Important Safety Information on pages 23-25. Please read full Prescribing Information, including Boxed Warning, and Medication Guide for TALVEY®.

Keeping track of treatment
 Keeping track of how you're feeling and your progress on treatment can help you throughout your treatment journey.
 Share this tracker with your healthcare team at your follow-up appointments.

Date	How are you feeling?	Notes
03/29/24	Food tasted off	Can I do anything to make food taste better?

IMPORTANT SAFETY INFORMATION (cont'd)

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

- **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.

Please read accompanying full Prescribing Information, including Boxed Warning, for TALVEY®.

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Please read full Important Safety Information on [pages 23-25](#). Please read full [Prescribing Information](#), including [Boxed Warning](#), and [Medication Guide](#) for TALVEY®.

IMPORTANT SAFETY INFORMATION

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)
- 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”)
- feeling sleepy
- feeling very sleepy with low energy
- slow or difficulty thinking
- seizures
- muscle weakness
- memory loss
- burning, throbbing, or stabbing pain

• 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 and 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.

Your care team will enroll you in the REMS program and provide you with a Patient Wallet Card to carry with you. You do not need to enroll in the REMS program.

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.

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

- have an infection

(continued on next page)

IMPORTANT SAFETY INFORMATION (cont'd)

Before you receive TALVEY®, tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

- 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 the 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 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

- **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:

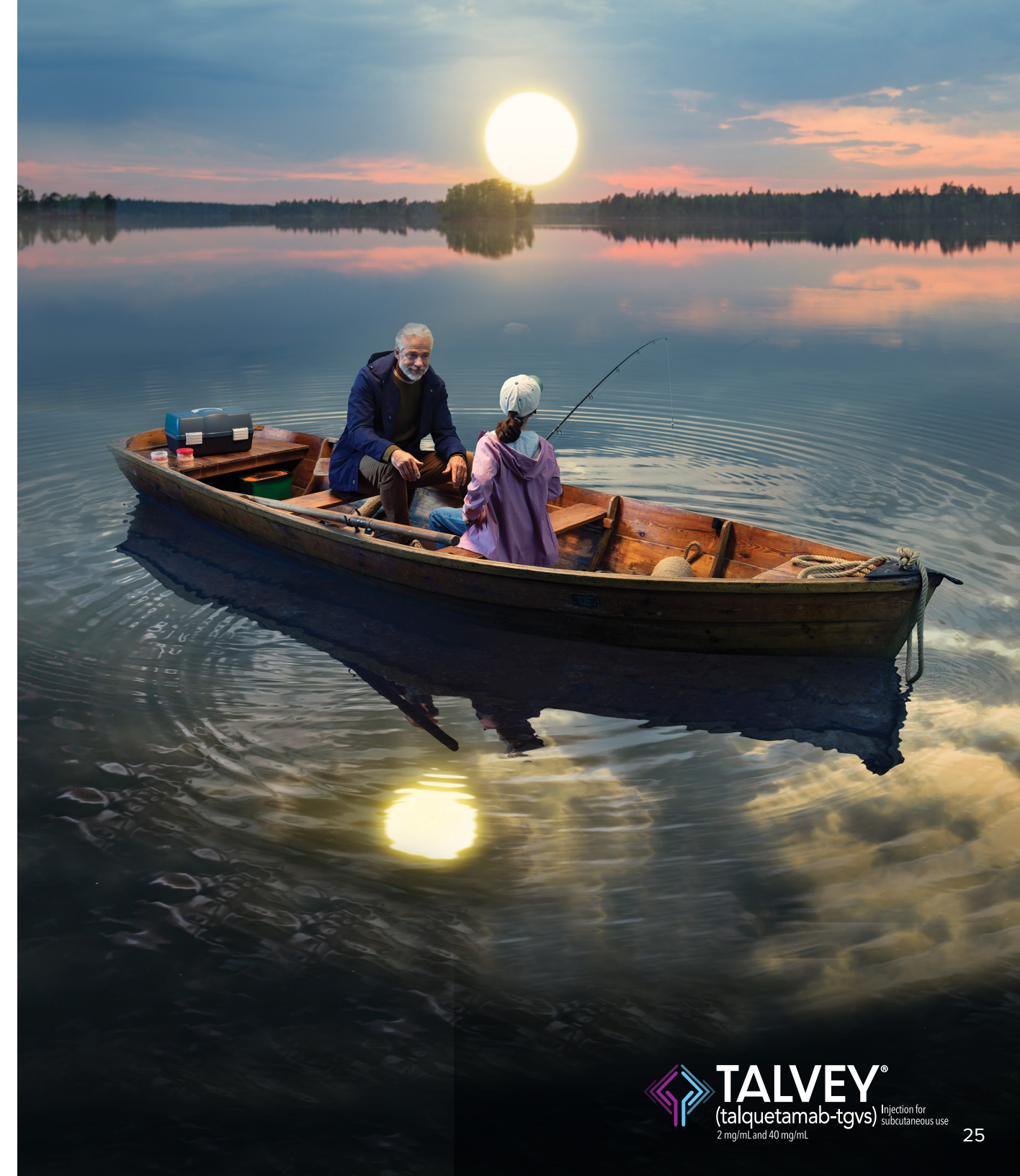
- changes in your sense of taste
- nail problems
- muscle and joint pain
- feeling very tired
- weight loss
- dry mouth
- fever
- very dry skin that may affect the mucous membranes (such as the mouth and eyes)
- difficulty swallowing
- infected nose, sinuses or throat (cold)
- diarrhea

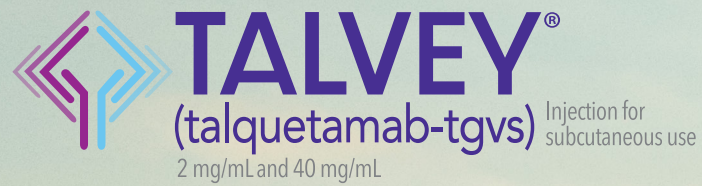
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Visit [TALVEY.com](https://www.talvey.com) to learn more and to sign up
for additional resources.

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