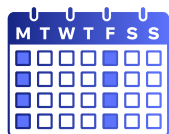


You've just taken a step forward in your tenosynovial giant cell tumor (TGCT) journey! Here's a guide to what you can expect when taking ROMVIMZA.



ROMVIMZA is for adults with symptomatic TGCT when surgery may make the symptoms worse or cause severe problems.



## Convenient, 2x weekly dosing

Take ROMVIMZA twice weekly, at least 72 hours apart. You do not take it every day.



Can be taken with or without food and has no known dietary restrictions.

Follow the dosing directions and schedule on your blister package and take ROMVIMZA on the same days each week.

### Important dosing instructions

- Take ROMVIMZA exactly as your healthcare provider tells you to
- Swallow ROMVIMZA capsules whole. Do not open, break, or chew the capsules
- Your healthcare provider may temporarily stop treatment, decrease your dose, or permanently stop treatment depending on how severe your side effects are
- Do not change your dose or stop taking ROMVIMZA unless your healthcare provider tells you to
- If you take more than the prescribed dose of ROMVIMZA, call your healthcare provider
- If you miss a dose of ROMVIMZA by 48 hours or less, take the missed dose as soon as possible and take the next dose on its regularly scheduled day. If you miss your dose by more than 48 hours, skip the missed dose, and take the next dose on its regularly scheduled day
- If you vomit within 30 minutes of taking a dose of ROMVIMZA, take another dose. If you vomit more than 30 minutes after taking your dose, do not take another dose and take the next dose on its regularly scheduled day
- Tell your healthcare provider about all your medical conditions, including if you:
  - have or had liver problems
  - are pregnant or plan to become pregnant. ROMVIMZA can harm your unborn baby
- **Females who are able to become pregnant:**
  - Your healthcare provider will do a pregnancy test before you start treatment with ROMVIMZA
  - Use effective birth control (contraception) during treatment with ROMVIMZA and for 1 month after the last dose. Talk to your healthcare provider about birth control methods that may be right for you
  - Tell your healthcare provider right away if you become pregnant or you think you may be pregnant during treatment with ROMVIMZA

**Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements**

Want more information? Visit [ROMVIMZA.com/dosing](https://ROMVIMZA.com/dosing)

### What is ROMVIMZA?

ROMVIMZA is a prescription medicine used to treat adults with symptomatic tenosynovial giant cell tumor (TGCT) when surgery may make the symptoms worse or cause severe problems.

It is not known if ROMVIMZA is safe and effective in children.

### SELECT SAFETY INFORMATION

#### What is the most important information I should know about ROMVIMZA?

**ROMVIMZA can cause serious side effects, including liver problems.** Increased liver enzymes in your blood are common with ROMVIMZA.

Please see [additional Safety Information throughout and click for the full Prescribing Information, including Medication Guide.](#)

Your healthcare provider will do blood tests to check for liver problems:

- before starting treatment with ROMVIMZA,
- 2 times each month for the first 2 months of treatment,
- then 1 time every 3 months for the first year of treatment and as clinically indicated thereafter.

If you develop liver problems during treatment with ROMVIMZA, your healthcare provider may temporarily stop treatment, decrease your dose, or permanently stop treatment depending on how severe your liver problems are.

- Tell your healthcare provider right away if you develop any signs or symptoms of liver problems during treatment with ROMVIMZA including yellowing of your skin or the white part of your eyes, dark urine, lack or loss of appetite, right upper stomach-area (abdomen) pain or tenderness, feeling overly tired, nausea, vomiting, fever, rash, and itching.

## In the clinical trial for ROMVIMZA, the most common side effects include:

- swelling around your eyes
- tiredness
- rash
- increased cholesterol levels in your blood
- swelling of your hands or feet
- swelling of your face
- decreased white blood cells
- itchy skin

## The majority of lab abnormalities were mild-to-moderate

No patients stopped because of lab abnormalities in MOTION

If you experience lab abnormalities, talk to your care team for guidance. In the clinical trial for ROMVIMZA, the majority of lab abnormalities were mild-to-moderate.

Increased liver enzymes in your blood are common with ROMVIMZA.

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If you develop liver problems during treatment with ROMVIMZA, your healthcare provider may temporarily stop treatment, decrease your dose, or permanently stop treatment depending on how severe your liver problems are.

Tell your healthcare provider right away if you develop any signs or symptoms of liver problems during treatment with ROMVIMZA including:

- yellowing of your skin or the white part of your eyes
- dark urine
- lack or loss of appetite
- right upper stomach-area (abdomen) pain or tenderness
- feeling overly tired
- nausea
- vomiting
- fever
- rash
- itching

## ROMVIMZA does not require a REMS program.\*

\*Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

## In the clinical trial, most people were able to start and stay on ROMVIMZA

**4.8%**  
(4 out of 83 people)

of patients stopped using ROMVIMZA because of side effects

39% of patients who took ROMVIMZA lowered their dose and 40% of patients had a dose interruption because of an adverse reaction or lab abnormality

**It's important that you talk to your healthcare provider if you experience a side effect, because there may be something they can do to help.**

### SELECT SAFETY INFORMATION

**Before taking ROMVIMZA, tell your healthcare provider about all of your medical conditions, including if you:**

- have or had liver problems.
- are pregnant or plan to become pregnant. ROMVIMZA can harm your unborn baby.

### Females who are able to become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with ROMVIMZA.
- Use effective birth control (contraception) during treatment with ROMVIMZA and for 1 month after the last dose. Talk to your healthcare provider about birth control methods that may be right for you.
- Tell your healthcare provider right away if you become pregnant or you think you may be pregnant during treatment with ROMVIMZA.

Please see [additional Safety Information](#) throughout.

## IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about ROMVIMZA?

**ROMVIMZA can cause serious side effects, including liver problems.** Increased liver enzymes in your blood are common with ROMVIMZA.

Your healthcare provider will do blood tests to check for liver problems:

- before starting treatment with ROMVIMZA,
- 2 times each month for the first 2 months of treatment,
- then 1 time every 3 months for the first year of treatment and as clinically indicated thereafter.

If you develop liver problems during treatment with ROMVIMZA, your healthcare provider may temporarily stop treatment, decrease your dose, or permanently stop treatment depending on how severe your liver problems are.

- Tell your healthcare provider right away if you develop any signs or symptoms of liver problems during treatment with ROMVIMZA including yellowing of your skin or the white part of your eyes, dark urine, lack or loss of appetite, right upper stomach-area (abdomen) pain or tenderness, feeling overly tired, nausea, vomiting, fever, rash, and itching.

### Before taking ROMVIMZA, tell your healthcare provider about all of your medical conditions, including if you:

- have or had liver problems.
- are pregnant or plan to become pregnant. ROMVIMZA can harm your unborn baby.

### Females who are able to become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with ROMVIMZA.
- Use effective birth control (contraception) during treatment with ROMVIMZA and for 1 month after the last dose. Talk to your healthcare provider about birth control methods that may be right for you.
- Tell your healthcare provider right away if you become pregnant or you think you may be pregnant during treatment with ROMVIMZA.

### Males with female partners who are able to become pregnant:

- Use effective birth control (contraception) during treatment with ROMVIMZA and for 1 month after the last dose.
- Tell your healthcare provider right away if your female partner becomes pregnant or thinks she may be pregnant during treatment with ROMVIMZA.

- are breastfeeding or plan to breastfeed. It is not known if ROMVIMZA passes into your breast milk. Do not breastfeed during treatment with ROMVIMZA and for 1 month after the last dose.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking ROMVIMZA with certain other medicines may affect the way that ROMVIMZA or the other medicine works and may increase your risk of side effects.

### What are the possible side effects of ROMVIMZA?

**ROMVIMZA can cause serious side effects.**

- **Allergic reactions to FD&C Yellow No. 5 and FD&C Yellow No. 6.** ROMVIMZA 20 mg capsules contain the inactive ingredients FD&C Yellow No. 5 (tartrazine) and FD&C Yellow No. 6 (Sunset Yellow FCF). ROMVIMZA 14 mg capsules contain the inactive ingredient FD&C Yellow No. 6 (Sunset Yellow FCF). FD&C Yellow No. 5 (tartrazine) can cause allergic-type reactions (including bronchial asthma) in certain people, especially people who also have an allergy to aspirin. FD&C Yellow No. 6 (Sunset Yellow FCF) can also cause allergic reactions. Tell your healthcare provider if you get hives, rash, or trouble breathing during treatment with ROMVIMZA.

**The most common side effects of ROMVIMZA include:**

- swelling around your eyes
- tiredness
- rash
- increased cholesterol levels in your blood
- swelling of your hands or feet
- swelling of your face
- decreased white blood cells
- itchy skin

ROMVIMZA may cause fertility problems, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of ROMVIMZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### What is ROMVIMZA?

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**Please click for the full Prescribing Information, including Medication Guide.**