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.

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.

Please see additional Safety Information throughout and click for the full Prescribing Information, including Medication Guide.

TABLE OF CONTENTS

What is tenosynovial giant cell tumor (TGCT)?

TGCT, also formerly known as pigmented villonodular synovitis (PVNS) or giant cell tumor of the tendon sheath (GCT-TS), is a rare, locally aggressive, tumor of the joint, specifically in the synovium, tendon sheath, or bursae.

11-50 cases

per million people annually

33 years of age

the median age of diagnosis

There are two types of TGCT:

- **Localized/nodular TGCT** is more common and tends to be smaller, well-defined tumors inside or outside of the joint
- **Diffuse TGCT** is less common and tends to be larger tumors with ill-defined boundaries

See the glossary on page 20 to better understand these terms.

High recurrence can potentially create lifelong burdens

UP TO **72%**
recurrence rate for diffuse

UP TO **15%**
recurrence rate for localized/nodular

TGCT leads to pain, swelling, and limited range of motion in the affected joint.

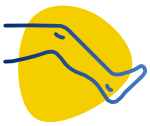
The condition may cause permanent damage to the joint.*

*In a study of patients with diffuse TGCT, 8 out of 45 patients (18%) who did not have osteoarthritis at baseline developed signs of joint damage.

TGCT can have a serious impact on people's lives

Because of pain and limitation of movement, people living with TGCT can have a decreased quality of life. Symptoms can limit daily activities.

92%
of patients reported pain



85%
of patients reported limited range of motion

In a recent study of people living with TGCT*

~55% OF PATIENTS
had their symptoms come back, even after surgery

*This study is from the TGCT Support Registry, the largest registry of TGCT patients. 497 adults were included in the analysis.

TGCT is often treated with surgery, but surgery isn't right for everyone

Not all tumors can be removed. Each additional surgery increases risks of complications and other health challenges. The choice between surgery and prescription treatment is up to you and your healthcare provider.

TGCT can have a major impact on daily living

What is ROMVIMZA?

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

See how ROMVIMZA fits into your life

ROMVIMZA is a TGCT treatment proven to reduce tumors and improve range of motion, physical function, and pain.

ROMVIMZA is an oral TGCT treatment that:

- Does not require a REMS (a specific type of drug safety program)
- Can be taken with or without food and has no known dietary restrictions
- Can be used with hormonal contraceptives. Use effective birth control during treatment and for 1 month after the last dose

You can take ROMVIMZA if:

- You have symptomatic TGCT and surgery may make the symptoms worse or cause severe problems
- You've had multiple surgeries or no prior surgery
- You've used other prescription or over-the-counter medicines for TGCT or its symptoms

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.

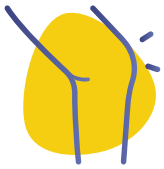
  Females who are able to become pregnant:
  - Your healthcare provider will do a pregnancy test before you start treatment with ROMVIMZA.
  - Use effective birth control (contraception) during treatment with ROMVIMZA and for 1 month after the last dose. Talk to your healthcare provider about birth control 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.

ROMVIMZA was studied in one of the largest placebo-controlled clinical trials for TGCT

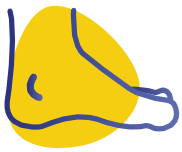
- The trial compared ROMVIMZA to placebo (a pill with no active medication)
- In MOTION, the clinical trial for ROMVIMZA, tumor response was measured using Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 at 25 weeks (approximately 6 months)
- The trial included 123 participants with symptomatic TGCT for whom surgery could have made the symptoms worse or caused severe problems
- The trial included participants who had previous surgeries and participants without previous surgeries

Tumor locations included



Knee

Hip



Ankle

Foot, wrist, hand, shoulder, elbow, and temporomandibular joint (which connects the lower jaw to the skull)

	Knee	Hip	Ankle	Foot, wrist, hand, shoulder, elbow, and temporomandibular joint (which connects the lower jaw to the skull)
ROMVIMZA n=83	56	11	9	7
Placebo n=40	27	1	6	6

SELECT SAFETY INFORMATION

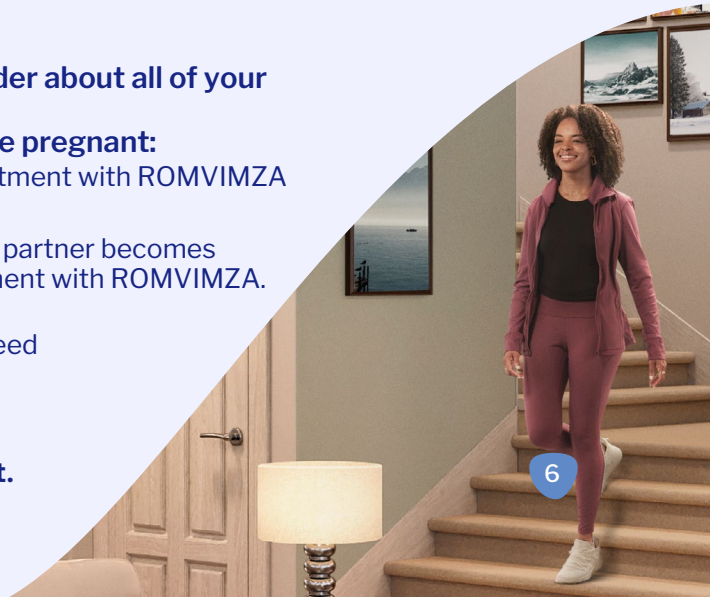
Before taking ROMVIMZA, tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

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.

Please see additional Safety Information throughout.

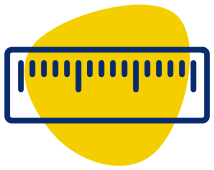


ROMVIMZA showed robust tumor reduction when compared to placebo

Objective response rates at 6 months*

Tumor response was measured in the 123 participants (some given placebo) in 2 ways:

TUMOR **LENGTH:**



40%

of people taking ROMVIMZA experienced a tumor response (vs 0% taking placebo)

(33 out of 83 people)

- 35% had partial tumor shrinkage by at least 30%
- 5% had their tumors disappear completely

Assessed using RECIST v1.1

TUMOR **VOLUME:**

67%

of people taking ROMVIMZA experienced a tumor response (vs 0% taking placebo)

(56 out of 83 people)

- 63% had partial tumor shrinkage by at least 50%
- 5% had their tumors disappear completely

Assessed using Tumor Volume Score (TVS)

*Study endpoints were measured at 25 weeks, which is approximately 6 months.

SELECT SAFETY INFORMATION

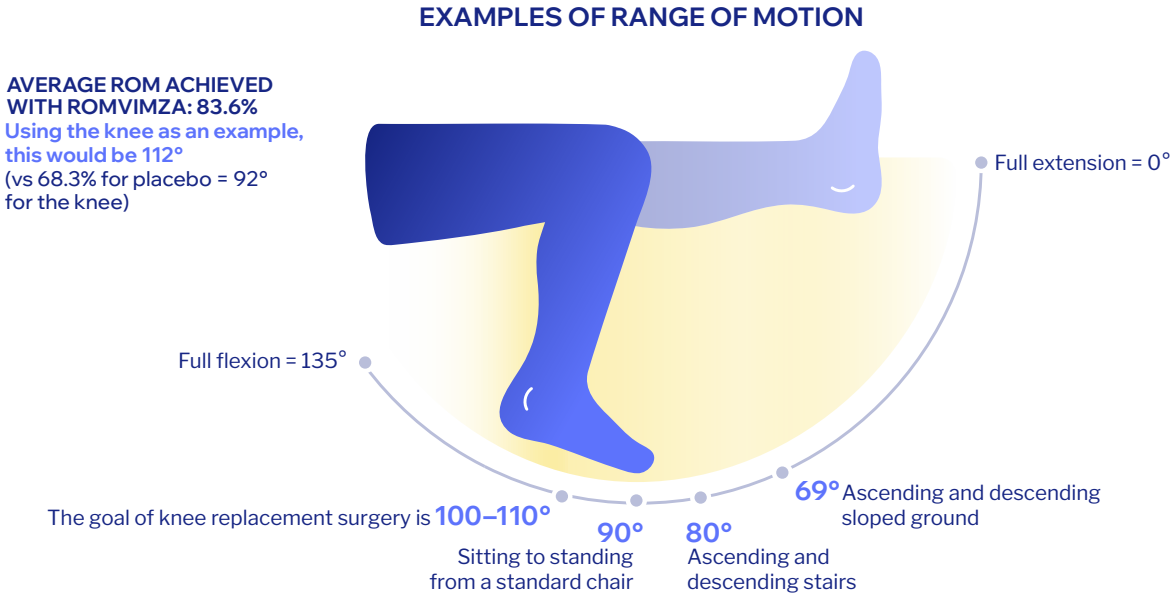
Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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.

Please see additional Safety Information throughout.

Range of motion (ROM) improved 18.4% in patients taking ROMVIMZA vs 3.8% in patients taking placebo

5x greater improvement in ROM was demonstrated in patients taking ROMVIMZA vs placebo at 6 months



SELECT SAFETY INFORMATION

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.

Please see additional Safety Information throughout.

Romvimza™ (vimseltinib) 30mg Capsules

ROMVIMZA™ (vimseltinib)

is an approved treatment that's proven to shrink tumors AND improve TGCT symptoms

SELECT SAFETY INFORMATION

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.

Please see additional Safety Information throughout.

ROMVIMZA goes beyond tumor reduction

At approximately 6 months

Physical function

Patients taking ROMVIMZA reported significant improvement in physical function compared to those taking placebo
(4.6 vs 1.3 point improvement in PROMIS-PF at week 25)

More patients taking ROMVIMZA reported clinically meaningful improvement in physical function than placebo
(43% vs 25%)

Based on the results of PROMIS-PF, a questionnaire in which clinical trial participants were asked to grade their ability to perform their normal daily activities.

Pain

Significantly more patients taking ROMVIMZA had a response in worst pain compared to those taking placebo
(48% vs 23%)

Response was at least a 30% improvement in their worst pain without increasing their use of pain medications by 30% or more.

Even those taking ROMVIMZA who did not have a tumor response experienced improvements in range of motion, pain, and/or physical function.*

*Limitations: This was an exploratory analysis, meaning it was not specifically designed to find differences. Therefore, these results may be due to chance and should be interpreted carefully. Individual results may vary from the clinical trial experience.

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.

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.

Please see additional Safety Information throughout.

TGCT treatment with a manageable safety profile

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

Swelling around the eyes	60%
Tiredness	59%
Rash	47%
Swelling of hands or feet	33%
Swelling of the face	31%
Itchy skin	29%

The majority of lab abnormalities were mild-to-moderate

No patients stopped because of lab abnormalities in MOTION

	Incidence and CTCAE Grades*			
	Vimseltinib N=83		Placebo N=39	
Laboratory Abnormality	**All Grades (%)**	**Grades 3 or 4 (%)**	**All Grades (%)**	**Grades 3 or 4 (%)**
Increased AST	92	0	11	0
Increased cholesterol	43	0	16	0
Decreased neutrophils	31	1	3	0
Decreased leukocytes	29	0	8	0
Increased ALT	24	0	16	0

*The severity of adverse drug reactions was assessed using CTCAE Version 5.0.
ALT=alanine aminotransferase; AST=aspartate aminotransferase; CTCAE=Common Terminology Criteria for Adverse Events.

- Increased liver enzymes in your blood are common with ROMVIMZA
- 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

SELECT SAFETY INFORMATION

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

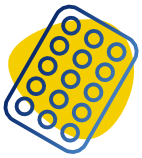
- have or had liver problems.
- are pregnant or plan to become pregnant. ROMVIMZA can harm your unborn baby.

Please see additional Safety Information throughout.

TGCT treatment with a manageable safety profile

- **No cases of drug-induced liver damage** were reported by patients taking 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 and during treatment.

- **No hair color changes** were seen in patients taking ROMVIMZA in the pivotal clinical trial



- **ROMVIMZA can be used with hormonal contraceptives.** Use effective contraception of your choice during treatment and for 1 month after the last dose

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

4.8% of patients stopped using ROMVIMZA because of side effects

(4 out of 83 people)

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.

SELECT SAFETY INFORMATION

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.

Take a step forward with ROMVIMZA

The only FDA-approved TGCT treatment with no known dietary restrictions.

You can take ROMVIMZA **with or without food**

No planning meals around ROMVIMZA since there are no known dietary restrictions*

*There are no known restrictions on consuming grapefruit or dairy products.

Convenient, 2x weekly dosing

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

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

ROMVIMZA can fit easily into your daily routine

Take ROMVIMZA exactly as prescribed. Even if you are feeling better, do not discontinue treatment without first consulting your healthcare provider.

SELECT SAFETY INFORMATION

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

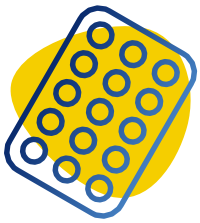
Males with female partners who are able to become pregnant:

- 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.

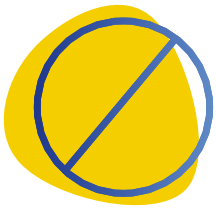
- are breastfeeding or plan to breastfeed. It is not known if ROMVIMZA passes into your breast milk. Do not breastfeed during treatment with ROMVIMZA and for 1 month after the last dose.

Please see additional Safety Information throughout.

Other 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

WHAT IF I VOMIT OR MISS A DOSE?

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.

SELECT SAFETY INFORMATION

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.

Please see additional Safety Information throughout.

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

For 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 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:

- 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
- Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine

SELECT SAFETY INFORMATION

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.

Please see additional Safety Information throughout.

Questions you may have about taking ROMVIMZA

Are there certain foods or drinks I should avoid when taking ROMVIMZA?

There are no known dietary restrictions when taking ROMVIMZA.

How long will I take ROMVIMZA?

Take ROMVIMZA exactly as your healthcare provider tells you to. 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.

How should I store ROMVIMZA?

- Store ROMVIMZA capsules at room temperature between 68°F to 77°F (20°C to 25°C)
- Store ROMVIMZA capsules in the original blister pack until you are ready to take them. Do not store ROMVIMZA capsules in another container
- The blister packs are child resistant. Keep ROMVIMZA and all medicines out of the reach of children

Are there any allergic reactions to be aware of with ROMVIMZA?

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.

Keep ROMVIMZA and all medicines out of the reach of children.

SELECT SAFETY INFORMATION

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.

Please see additional Safety Information throughout.

decīphera AccessPoint™

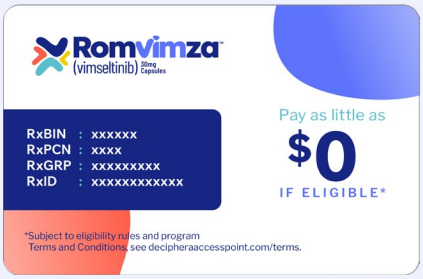
Romvimza™ (vimseltinib) 30mg Capsules

Deciphera AccessPoint is here to help you start on ROMVIMZA

Insurance questions? Cost concerns? Let us point the way.

Financial help may be available no matter what insurance you have, or if you have no insurance at all:

- If you have non-government insurance, such as through an employer, the **Commercial Copay Program** may cover ALL your out-of-pocket drug costs (as little as $0 copay)*
- If you don't have insurance, or if your health plan doesn't cover ROMVIMZA, you may qualify for **free medication***
- Case Managers are available to help patients **understand their benefits** and other resources that may be available to them
- **Rapid Start Program**: If eligible, you can start on ROMVIMZA if your insurance is delayed in making a coverage decision*
- **Bridge Program**: Get help staying on ROMVIMZA if your insurance changes or there's a gap in your coverage*



*Terms and conditions apply. Not every patient is eligible. Copay program is subject to an annual benefit maximum.

Call us directly

Call 1-833-4DACCES to speak to a dedicated Case Manager (1-833-432-2237) Monday–Friday 8AM–8PM ET

Visit our website

DecipheraAccessPoint.com

Send an email

info@decipheraaccesspoint.com to schedule a call back

How to talk to your healthcare provider about taking ROMVIMZA

You and your care team are all working together. Discussing your treatment, including any side effects you may have, can help your healthcare provider and your care team help you.

Here are some questions you may want to ask your healthcare provider:

- What can I do to prepare for my treatment?
- What can I expect from my treatment?
- How will I know if my treatment is working?
- Will I need any lab tests or procedures during my treatment?
- Will I need to adjust my daily activities or responsibilities?
- What are the side effects? How long might these last?
- What should I do if I experience side effects or symptoms?
- Will any medicine or substances I'm taking affect my treatment?
- If I have any questions, what's the best way to get in touch?
- Who should I contact in case of emergency, and how?

Starting the conversation with your healthcare provider about treatment is the first step in your ROMVIMZA journey.

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.

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.

Please see additional Safety Information throughout.

Tracking your symptoms and side effects

All the symptoms and side effects you experience are important. Use this page to start a log to record them and then discuss with your healthcare provider and care team.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Symptom or side effect

Date _____ Time _____

Duration _____

Symptom or side effect

Date _____ Time _____

Duration _____

Symptom or side effect

Date _____ Time _____

Duration _____

Symptom or side effect

Date _____ Time _____

Duration _____

Download the doctor discussion guide.

This tool can help lead your conversation on ROMVIMZA and keep track of how it's helping.

Glossary of common terms related to TGCT

Bursa (plural, bursae): these are fluid-filled sacs lubricating the area between bone and bone, and soft tissue such as muscles and tendons. The sac functions to reduce wear and tear of the joint.

Clinical trial: a research study that uses human participants to extend scientific knowledge of a disease or treatment.

Colony stimulating factor 1 (CSF1): a protein highly produced in TGCT.

Joint: a region where two bones meet to allow different types of movement.

Objective response rate (ORR): the percentage of patients that had a partial or complete response to a treatment in a clinical trial.

Range of motion (ROM): the mobility or flexibility of a joint. This can be measured as the direction and degrees in which a joint can move.

Recurrence: is the reappearance of a tumor following treatment.

Synovium: soft tissue that lines the cavity of some joints, tendon sheaths, and bursae. The synovium lines the inner surface of the joint.

Tendon: a cord of strong, flexible tissue (like a rope) that connects your muscles to your bones and allows movement of limbs.

Tendon sheath: a layer of connective tissue around a tendon. A tendon is able to slide inside the tendon sheath which allows it to move smoothly without getting stuck.

Tenosynovial giant cell tumor (TGCT): locally aggressive, rare tumor disease occurring in and surrounding the joint, tendon sheath, and bursae. There are two types: diffuse TGCT and localized/nodular TGCT.

Tumor: an abnormal growth of cells that forms a solid mass. Tumors can be benign or malignant, meaning cells can grow to invade nearby tissues and spread to other parts of the body.

IMPORTANT SAFETY INFORMATION

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- 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?

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.

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

Resources that can help

Living with TGCT may be challenging, but finding information and support doesn't have to be.

TGCT TRUTH

Visit TGCTtruth.com for more information and support.
(a Deciphera-sponsored website)

TGCT Support

NORD® National Organization for Rare Disorders

SFA SARCOMA FOUNDATION of AMERICA

CANCERcare®

Deciphera is not associated with or connected to any of these organizations.

ROMVIMZA is here to help you move forward with TGCT

MyRomvimza

Prescribed ROMVIMZA?
For those prescribed ROMVIMZA, MyROMVIMZA can help patients with medication trackers, appointment reminders, and more. **Find the access code to register with MyROMVIMZA in your ROMVIMZA welcome kit.**

Download the app

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