Romvimza® (vimseltinib) 30mg Capsules

A GUIDE FOR U.S. HEALTHCARE PROVIDERS

Supporting patients and setting treatment expectations

with ROMVIMZA® (vimseltinib)

NCCN CATEGORY 1 PREFERRED

Vimseltinib (ROMVIMZA) is a Category 1 Preferred systemic therapy option for patients with TGCT[1]

NCCN=National Comprehensive Cancer Network® (NCCN®); U.S.=United States.

INDICATIONS AND USAGE

ROMVIMZA is indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hepatotoxicity:

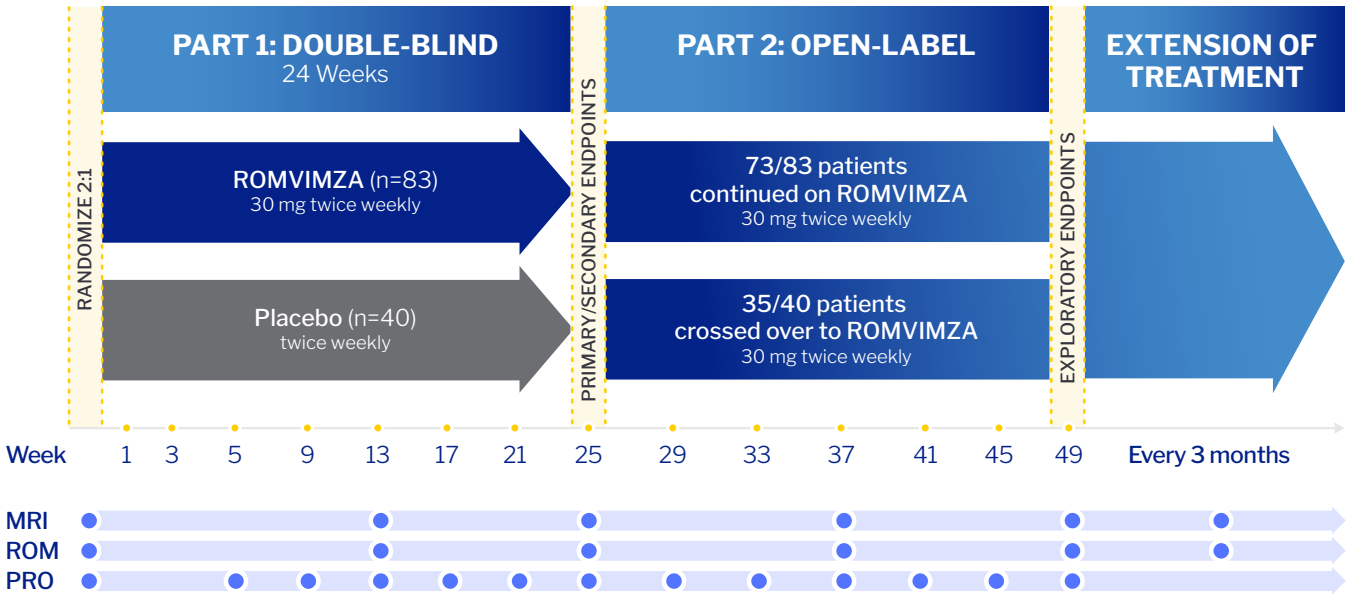
- Cases of serious and fatal liver injury have occurred with the use of another kinase inhibitor that targets CSF1R. Serious and fatal liver injury have not been observed with ROMVIMZA.
- Elevated AST and ALT can occur with ROMVIMZA.
- Avoid ROMVIMZA in patients with pre-existing increased serum transaminases; total bilirubin or direct bilirubin (>ULN); or active liver or biliary tract disease, including ALP.
- Monitor liver function tests prior to initiation of ROMVIMZA, twice a month for the first two months and once every 3 months for the first year of therapy and as clinically indicated thereafter. Withhold and reduce the dose, or permanently discontinue ROMVIMZA based on the severity of the hepatotoxicity.

Please see additional Safety Information throughout and please click for the full Prescribing Information.

MOTION: A global multicenter, randomized, double-blind, placebo-controlled, phase 3 study in 123 patients with symptomatic TGCT[2,3]

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STUDY DESIGN[2-4]



Key eligibility criteria[4]

- Patients 18 years or older
- Confirmed diagnosis of symptomatic TGCT for which surgical resection would potentially cause worsening functional limitation or severe morbidity

Key exclusion criteria[4]

- Previous use of systemic therapy (investigational or approved) targeting CSF1 or CSF1R
  - Previous treatment with imatinib or nilotinib was allowed

CSF1=colony-stimulating factor 1; CSF1R=colony-stimulating factor 1 receptor; MRI=magnetic resonance imaging; PRO=patient-reported outcome; ROM=range of motion.

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WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity:

- ROMVIMZA may cause fetal harm when administered to pregnant women. Advise pregnant women on the potential risk tothe fetus.
- Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with ROMVIMZA and for 1 month after the last dose.

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Tumor response at Week 25 (6 months)[2]

Primary endpoint:

- ORR by RECIST v1.1 (tumor length) per IRR

Key secondary endpoint:

- ORR by TVS (tumor volume score) per IRR

Tumor response at ≥2 years[5]

- Tumor response was assessed by RECIST v1.1 per IRR and TVS per IRR

SYMPTOMATIC AND FUNCTIONAL OUTCOMES AT WEEK 25 (6 MONTHS)[2]

Additional key secondary endpoints:



ROM:
change from baseline in active ROM



Physical function:
change from baseline in PROMIS-PF



Pain:
patient-reported BPI-30 worst pain response rate

Long-term follow-up analysis limitations

- Open-label extension data should be considered descriptive in nature
- No conclusions of safety or efficacy should be made based on these results
- In an open-label extension, there is a potential for enrichment of the long-term data for the COAs in the remaining patient populations since patients who are unable to tolerate or do not respond to the drug often drop out
- Schedule of assessments for ROM and PROs changed after Week 49 so results are not comparable
- Long-term data are not included in the ROMVIMZA Prescribing Information

BPI=Brief Pain Inventory; COAs=clinical outcome assessments; IRR=independent radiological review; ORR=objective response rate; PROMIS-PF=Patient-Reported Outcomes Measurement Information System Physical Function (TGCT-specific); RECIST v1.1=Response Evaluation Criteria in Solid Tumors version 1.1; TVS=tumor volume score.

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WARNINGS AND PRECAUTIONS

Allergic Reactions to FD&C Yellow No. 5 (Tartrazine) and No. 6 (Sunset Yellow FCF):

- ROMVIMZA 20 mg capsule contains FD&C Yellow No. 5 (tartrazine) which may cause allergic reactions (including bronchial asthma) in certain susceptible patients. FD&C Yellow No. 5 (tartrazine) sensitivity is frequently seen in patients who also have aspirin sensitivity.
- Advise patients that ROMVIMZA 14 mg and 20 mg capsules contain FD&C Yellow No. 6 (Sunset Yellow FCF), which may cause allergic reactions.

Please see additional Safety Information throughout.

ROMVIMZA® (vimseltinib) demonstrated robust efficacy in MOTION at Week 25 (6 months)[2,3]



Robust tumor response vs placebo[2,3]

- **40% ORR by RECIST with ROMVIMZA** (33/83) vs 0% placebo (0/40) (5% CR; 35% PR; 95% CI: 29, 51; *P*<0.0001)
- **67% ORR by TVS with ROMVIMZA** (56/83) vs 0% placebo (0/40) (5% CR*; 63% PR*; 95% CI: 56, 77; *P*<0.0001)



Improved physical function[2]

- **4.6 points with ROMVIMZA** vs 1.3 points with placebo (95% CI: 1.4, 5.2; *P*=0.0007)



Reduction in patient-reported worst pain[2]

- **48% reduction** in BPI-30 worst pain vs 23% taking placebo (*P*=0.0056)



Improved range of motion[2,3]

- **18.4% with ROMVIMZA** (vs 3.8% with placebo (95% CI: 4.0, 25.3; *P*=0.0077)

*Percentages may not add up to ORR due to rounding.
CI=confidence interval; CR=complete response; PR=partial response.

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Increased Creatinine without Affecting Renal Function:

- Increases in serum creatinine can occur with the use of ROMVIMZA. These increases in serum creatinine may not be associated with changes in renal function. Increases in creatinine reversed upon ROMVIMZA discontinuation. During ROMVIMZA treatment, use alternative measures that are not based on serum creatinine to assess renal function.

Please see additional Safety Information throughout.

Setting expectations at treatment initiation may help patients stay on track with therapy[6,7]

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Earliest time at which improvements were seen generally aligned to the first scheduled assessment in MOTION

1 Month[8]



Pain & Physical Function
Improvements were seen in some patients as early as 5 weeks (1 month) and continued through 49 weeks

3 Months[8]



Range of Motion
Improvements were seen in some patients as early as 13 weeks (3 months) continued through 49 weeks

3 Months[2,5]



Tumor Response
Improvements were seen in some patients as early as 13 weeks (3 months)

with improvements continuing through ≥2 years of follow-up*

Nearly 1 in 4 patients were tumor-free at 2 years[5]

*Median (range) treatment duration was 23.6 months (2–36) for patients randomized to ROMVIMZA and 19.1 months (1–30) for those who crossed over to ROMVIMZA.[5]

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Adverse Reactions:

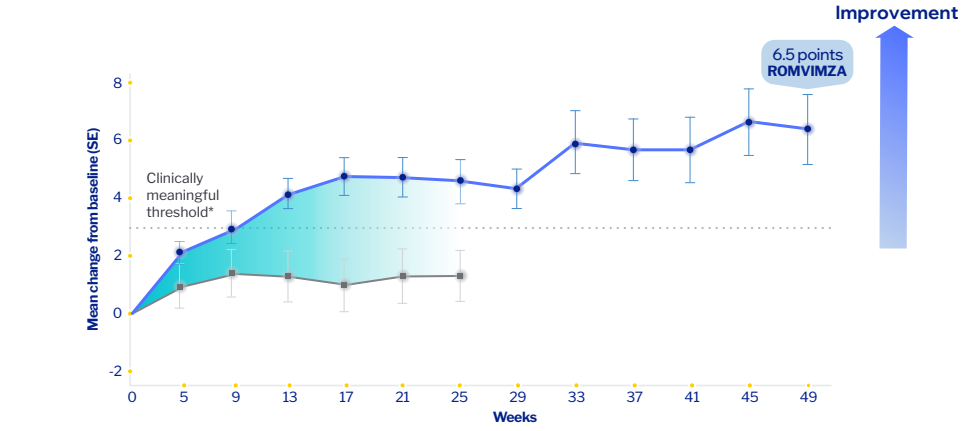
The most common (≥20%) adverse reactions, including laboratory abnormalities that occurred in patients receiving ROMVIMZA were increased AST, periorbital edema, fatigue, rash, increased cholesterol, peripheral edema, face edema, decreased neutrophils, decreased leukocytes, pruritus, and increased ALT.

Please see additional Safety Information throughout.

Supporting long-term treatment: Symptomatic improvement observed through 1 year of follow-up[8]

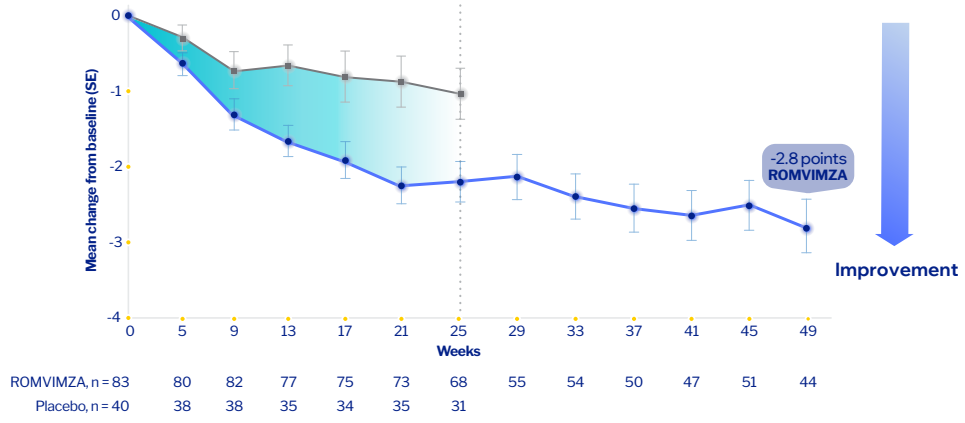
Improvements in **pain** and **physical function** were observed as **early as the first assessment** (Week 5)[8]

PHYSICAL FUNCTION (PROMIS-PF)[2-4,8]



- PROMIS-PF measures a patient's ability to do a range of daily activities[4]
- 15-item questionnaire assessed tumor location-specific (upper vs lower extremity) physical function[4]
- Data for PROMIS-PF is largely based on lower limb extremity assessment due to tumor location. Higher scores of PROMIS-PF indicate better physical functioning[2]

BPI WORST PAIN[8]



- Patients were asked to rate their worst pain in the last 24 hours on a scale of 0 (no pain) to 10 (pain as bad as you can imagine)[4]

*Clinically meaningful threshold: ≥3 point increase from baseline in PROMIS-PF score at Week 25.[2-4]
SE=standard error.

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Drug Interactions:

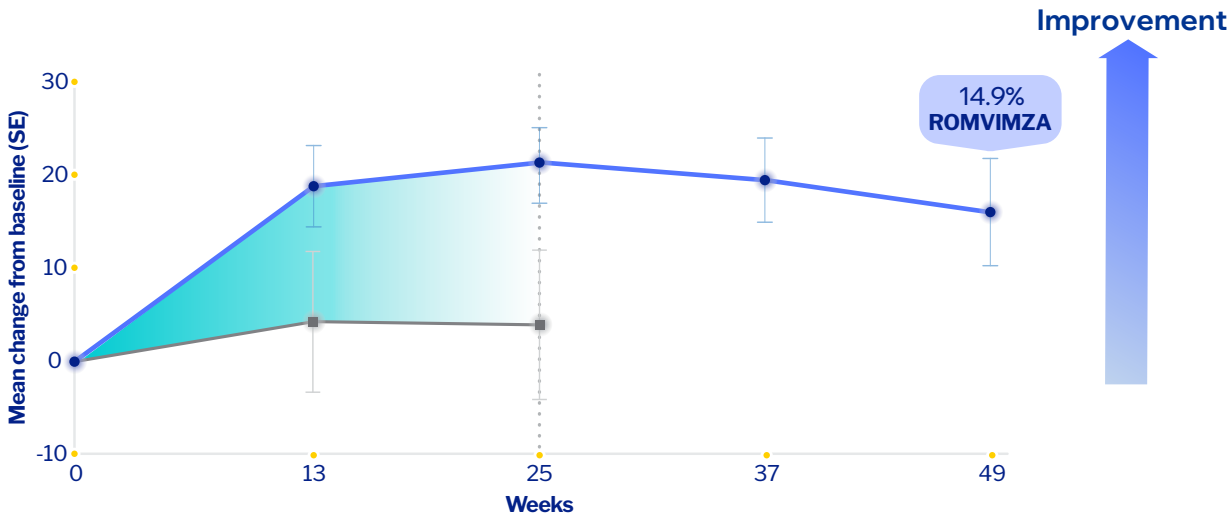
- P-glycoprotein (P-gp) substrates: Avoid concomitant use of ROMVIMZA with P-gp substrates. If concomitant use cannot be avoided, take ROMVIMZA at least 4 hours prior to P-gp substrates.
- Breast Cancer Resistance Protein (BCRP) substrates: Avoid concomitant use of ROMVIMZA with BCRP substrates.
- Organic Cation Transporter 2 (OCT2) substrates: Avoid concomitant use of ROMVIMZA with OCT2 substrates.
- Concomitant use of vimseltinib with P-gp substrates, BCRP substrates or OCT2 substrates may increase exposure of these substrates.

Lactation: Advise females not to breastfeed during treatment with ROMVIMZA.

Please see additional Safety Information throughout and please click for the full Prescribing Information.

Improvements in **active range of motion** were observed as **early as the first assessment** (Week 13)[8]

ACTIVE ROM[8]



ROMVIMZA, n = 79	75	73	60	54
Placebo, n = 38	34	33		

- These results reflect observed mean values and are provided as supportive context to the primary analysis
- In an open-label extension, there is a potential for enrichment of the long-term data for the COAs in the remaining patient populations since patients who are unable to tolerate or do not respond to the drug often drop out

SE=standard error.

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WARNINGS AND PRECAUTIONS

Hepatotoxicity:

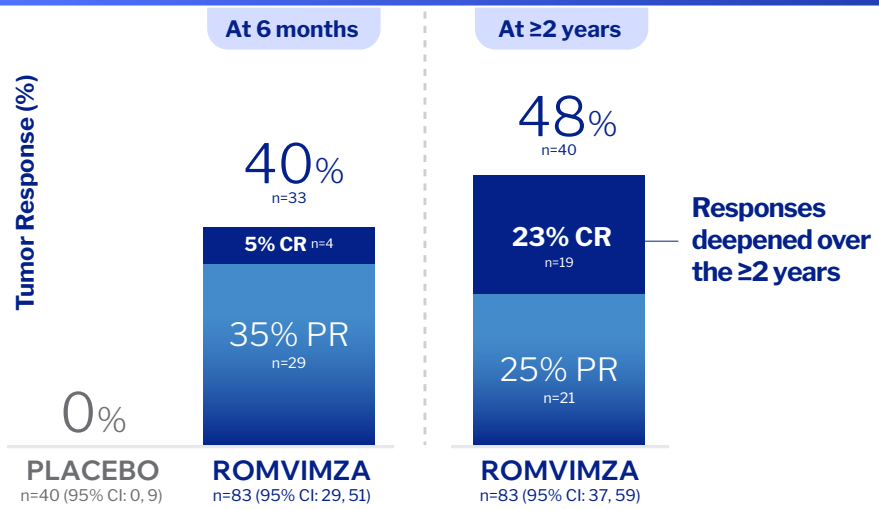
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Establishing long-term treatment considerations for patients on ROMVIMZA® (vimseltinib)

Tumor response was observed at 6 months, with **some patients responding as early as the first assessment** (Week 13)—with **improvements continuing** through ≥2 years of follow-up[2,5]

TUMOR RESPONSE BY RECIST[2,5]



CHANCE TO BE TUMOR-FREE:

Nearly 1 in 4 patients achieved a complete response at 2 years

The ORR by RECIST at ≥2 years for patients in the **crossover group was 54% (19/35)** (11% CR; 43% PR; 95% CI: 37, 71)

Tumor response by TVS[2,3,5]

- At Week 25 (6 months) **for patients on ROMVIMZA was 67% (56/83)** vs 0% on placebo (0/40) (5% CR*; 63% PR*; 95% CI: 56, 77)
- At ≥2 years **for patients on ROMVIMZA was 81% (67/83)** (24% CR; 57% PR; 95% CI: 71, 89)
- The ORR by TVS at ≥2 years for patients in the **crossover group was 71% (25/35)** (11% CR; 60% PR; 95% CI: 54, 85)

*Percentages may not add up to ORR due to rounding.

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WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity:

- ROMVIMZA may cause fetal harm when administered to pregnant women. Advise pregnant women on the potential risk to the fetus.
- Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with ROMVIMZA and for 1 month after the last dose.

Please see additional Safety Information throughout.

Individualized treatment plans

- The optimal treatment duration of ROMVIMZA has not been established. Treatment decisions should be determined through shared decision-making between a healthcare provider and their patient, taking into account considerations such as tumor response, symptomatic and functional improvements, tolerance, and patient preference[6]
- Over time, patients on ROMVIMZA may experience continued improvements in tumor response and in patient-reported and functional outcomes[5,8]
- If patients decide to stop treatment or take a treatment break, it's important to monitor patients as symptoms can reemerge and additional treatment may be appropriate[7]

Assessing patients after systemic treatments

- MRI is the technique of choice to detect recurrence and evaluate the dimensional changes of TGCT[6]
- Efficacy assessment may incorporate clinical, functional, and imaging assessments[6]

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- Advise patients that ROMVIMZA 14 mg and 20 mg capsules contain FD&C Yellow No. 6 (Sunset Yellow FCF), which may cause allergic reactions.

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95% of ARs were Grade 1 or 2[9]

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Adverse reactions (in ≥10%) at 6 months in the MOTION study[2]*

Adverse reaction†	ROMVIMZA (n=83)		Placebo (n=39)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Eye disorders				
Periorbital edema‡	60	3.6	21	0
Lacrimation increased	12	0	0	0
Dry eye‡	10	0	0	0
General disorders and administration site conditions				
Fatigue‡	59	1.2	38	2.6
Peripheral edema‡	33	1.2	8	0
Face edema	31	1.2	8	0
Skin and subcutaneous tissue disorders				
Rash‡	47	3.6	5	0
Pruritus	29	2.4	8	0
Vascular disorders				
Hypertension	17	4.8	10	2.6
Nervous system disorders				
Neuropathy‡	12	1.2	2.6	0

- At ≥2 years of follow-up of MOTION, ROMVIMZA continued to have a manageable safety profile with no new signals observed[5§]
- Other clinically significant reactions occurring in <10% of patients treated with ROMVIMZA include blurred vision (6%)[2]

*Adverse reactions occurring from baseline in ≥10% patients receiving ROMVIMZA and with a 5% difference between ROMVIMZA and placebo arms through Week 25 in the MOTION study.[2]
†The severity of adverse reactions was assessed using CTCAE Version 5.0.[2]
‡Includes multiple related terms.[2]
§Data cutoff: February 22, 2025.[5]
AR=adverse reaction; CTCAE=Common Terminology Criteria for Adverse Events.

Lab abnormalities (in ≥10%) at 6 months in the MOTION study[2]*

Laboratory abnormality[†‡]	ROMVIMZA (n=83)		Placebo (n=39)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Chemistry				
AST increased	92	0	11	0
Cholesterol increased	43	0	16	0
ALT increased	24	0	16	0
Creatinine increased	17	0	2.6	0
ALP increased	14	0	8	0
Magnesium increased	13	1.2	2.6	0
Calcium decreased	13	0	2.6	0
Hematology				
Neutrophils decreased	31	1.2	2.6	0
Leukocytes decreased	29	0	8	0

- Elevated AST and ALT can occur with ROMVIMZA[2]
- If a patient develops elevated AST and/or ALT during treatment on ROMVIMZA, consider temporarily stopping treatment, dose reduction, or permanently stopping treatment depending on how severe liver problems are[2]
- Additional clinically significant laboratory abnormality: *Increased Creatine Phosphokinase (CPK)*[2]

*Laboratory abnormalities worsening from baseline in ≥10% patients receiving ROMVIMZA and with a 5% difference between ROMVIMZA and placebo arms through Week 25 in the MOTION study.[2]
†The severity of adverse reactions was assessed using CTCAE Version 5.0.[2]
‡The denominator used to calculate the rate was 83 for ROMVIMZA and 38 for placebo based on the number of patients with a baseline value and at least one post-treatment value.[2]

ALP=alkaline phosphatase; ALT=alanine aminotransferase; AST=aspartate aminotransferase.

ROMVIMZA® (vimseltinib) offers convenient, twice-a-week, oral dosing with no known dietary restrictions[2]



Not actual size

THE RECOMMENDED DOSAGE OF ROMVIMZA IS

30 mg orally, taken twice weekly at least 72 hours apart, with or without food.



30 mg

Not actual size



20 mg

Not actual size



14 mg

Not actual size



Patients choose their Day 1 which dictates their Day 5. Their dosing days remain the same each week.

With ROMVIMZA, there's no:

- Known dietary restrictions (including grapefruit and dairy products) and can be taken with a high-fat meal
- REMS program requirement*

For females and males of reproductive potential:

- Use effective contraception during treatment and for one month after their last dose due to risks of embryo-fetal toxicity
  - ROMVIMZA can be used alongside all contraceptive methods, including hormonal birth control, allowing patients to continue with their preferred birth control method

MyRomvimza

Inform your patients of the MyROMVIMZA app: a tool that can help them with medication trackers, appointment reminders, and more.

*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.

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Increased Creatinine without Affecting Renal Function:

- Increases in serum creatinine can occur with the use of ROMVIMZA. These increases in serum creatinine may not be associated with changes in renal function. Increases in creatinine reversed upon ROMVIMZA discontinuation. During ROMVIMZA treatment, use alternative measures that are not based on serum creatinine to assess renal function.

Adverse Reactions:

The most common (≥20%) adverse reactions, including laboratory abnormalities that occurred in patients receiving ROMVIMZA were increased AST, periorbital edema, fatigue, rash, increased cholesterol, peripheral edema, face edema, decreased neutrophils, decreased leukocytes, pruritus, and increased ALT.

Please see additional Safety Information throughout.

Dose modifications were common—and can help patients stay on ROMVIMZA[2,6,7]

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Dose interruptions or dose reductions may be required based on a patient's safety and tolerability. Consider dose reductions as part of AR management to help maintain treatment continuity.[2,6,7]

The recommended dose modifications for adverse reactions are[2]:

1st dose reduction is **20 mg twice weekly**

2nd dose reduction is **14 mg twice weekly**

Permanently discontinue ROMVIMZA in patients who are unable to tolerate 14 mg orally twice weekly

ARs or laboratory abnormalities led to[2]:

- **Discontinuation in 4.8% (4 out of 83) of patients**
- Dose reductions in 39% (32 out of 83) of patients
- Dose interruptions in 40% (33 out of 83) of patients

Click here to view dosage modifications in the event of hepatotoxicity

SELECT SAFETY INFORMATION

Drug Interactions:

- P-glycoprotein (P-gp) substrates: Avoid concomitant use of ROMVIMZA with P-gp substrates. If concomitant use cannot be avoided, take ROMVIMZA at least 4 hours prior to P-gp substrates.
- Breast Cancer Resistance Protein (BCRP) substrates: Avoid concomitant use of ROMVIMZA with BCRP substrates.
- Organic Cation Transporter 2 (OCT2) substrates: Avoid concomitant use of ROMVIMZA with OCT2 substrates.
- Concomitant use of vimseltinib with P-gp substrates, BCRP substrates or OCT2 substrates may increase exposure of these substrates.

Lactation: Advise females not to breastfeed during treatment with ROMVIMZA.

Please see additional Safety Information throughout and please click for the full Prescribing Information.

Dose modifications were common—and can help patients stay on ROMVIMZA[2,6,7]

Recommended dosage modifications for hepatotoxicity in patients on ROMVIMZA[1]

Hepatotoxicity severity	ROMVIMZA dosage modifications
AST and/or ALT increases **>3–5 times ULN** **AND** total bilirubin increases up to **2 times ULN** **OR** Total bilirubin increases up to **2 times ULN**	• **Withhold ROMVIMZA until AST and ALT resolve** to baseline or ≤3 times ULN, and bilirubin resolves to baseline. • **Resume at the next lower dose level** once Hy's law has been definitively ruled out. • **Permanently discontinue** if adverse reaction does not resolve within 4 weeks.
AST and/or ALT increases **>3–5 times ULN,** **AND** total bilirubin increases **>2 times ULN** or INR **>1.5** and ALP **<2 times ULN** **OR** Total bilirubin increases **>2 times ULN**	• **Withhold ROMVIMZA until AST and ALT resolve** to baseline or ≤3 times ULN, and bilirubin resolves to baseline. • **Resume at the next lower dose level** once Hy's law has been definitively ruled out. • **Permanently discontinue** if adverse reaction does not resolve within 4 weeks.
AST and/or ALT increases **>5–8 times ULN** **AND** total bilirubin **≤ULN,** **AND** without clinical symptoms	• **Withhold ROMVIMZA until AST and ALT resolve** to baseline or ≤3 times ULN. • **Resume at the next lower dose level.** • **Permanently discontinue** if adverse reaction does not resolve within 4 weeks.
AST and/or ALT increases **>5–8 times ULN** **AND** total bilirubin increases **>ULN,** or INR **>1.5,** or ALP **>2 times ULN**	**Permanently discontinue** ROMVIMZA.
AST and/or ALT increases **>8 times ULN**	**Permanently discontinue** ROMVIMZA.

ALP=alkaline phosphatase; ALT=alanine aminotransferase; AST=aspartate aminotransferase; INR=international normalized ratio; ULN=upper limit of normal.

Reference: 1. ROMVIMZA [package insert]. Waltham, MA: Deciphera Pharmaceuticals, LLC.

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Drug Interactions:

- P-glycoprotein (P-gp) substrates: Avoid concomitant use of ROMVIMZA with P-gp substrates. If concomitant use cannot be avoided, take ROMVIMZA at least 4 hours prior to P-gp substrates.
- Breast Cancer Resistance Protein (BCRP) substrates: Avoid concomitant use of ROMVIMZA with BCRP substrates.
- Organic Cation Transporter 2 (OCT2) substrates: Avoid concomitant use of ROMVIMZA with OCT2 substrates.
- Concomitant use of vimseltinib with P-gp substrates, BCRP substrates or OCT2 substrates may increase exposure of these substrates.

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AR Management:

Edema: Periorbital, peripheral, or facial[10]

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Disorders characterized by swelling due to an excessive accumulation of fluid around the eyes (periorbital), extremities (peripheral), or face (facial).[10]

Periorbital edema

Severity[10]*	In the MOTION trial[2]	
	Rate in ROMVIMZA-treated patients	Rate in placebo-treated patients
Grade 1: Soft or non-pitting	**Grade 1 or 2:** 56.4%	Grade 1 or 2: 21%
Grade 2: Indurated or pitting edema		
Grade 3: Edema associated with visual disturbance; increased intraocular pressure, glaucoma or retinal hemorrhage; optic neuritis; diuretics indicated; operative intervention indicated	3.6%	0%

Peripheral edema

Severity[10]*	In the MOTION trial[2]	
	Rate in ROMVIMZA-treated patients	Rate in placebo-treated patients
Grade 1: 5–10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection	**Grade 1 or 2:** 31.8%	Grade 1 or 2: 8%
Grade 2: >10–30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental ADL		
Grade 3: >30% inter-limb discrepancy in volume; gross deviation from normal anatomic contour; limiting self-care ADL	1.2%	0%

Facial edema

Severity[10]*	In the MOTION trial[2]	
	Rate in ROMVIMZA-treated patients	Rate in placebo-treated patients
Grade 1: Localized facial edema	**Grade 1 or 2:** 29.8%	Grade 1 or 2: 8%
Grade 2: Moderate localized facial edema; limiting instrumental ADL		
Grade 3: Severe swelling; limiting self-care ADL	1.2%	0%

*Source: CTCAE Version 5.0 as was used in the MOTION trial.[2]
ADL=activities of daily living.

General tips and suggestions for supportive care for edema

Note: *These are general management tips and are not specific to ROMVIMZA, the MOTION study, or TGCT.*

- **Diuretics[11]:**
  May help remove excess fluid from the body to reduce swelling
- **Topical or systemic steroids[11]:**
  May help reduce inflammation and swelling
- **Dietary modifications[12]:**
  A low-salt diet and restricting fluid intake may help with fluid retention
- **Sleep position[12]:**
  If relevant, elevate impacted areas during sleep or rest
- **Cold compress[11]:**
  Cooling the impacted areas with a compress could provide comfort
- **Compression socks[13]:**
  Compression stockings and/or sleeves may assist with helping move extra fluid towards the center

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hepatotoxicity:

- Cases of serious and fatal liver injury have occurred with the use of another kinase inhibitor that targets CSF1R. Serious and fatal liver injury have not been observed with ROMVIMZA.
- Elevated AST and ALT can occur with ROMVIMZA.
- Avoid ROMVIMZA in patients with pre-existing increased serum transaminases; total bilirubin or direct bilirubin (>ULN); or active liver or biliary tract disease, including ALP.
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AR Management:

Pruritus and Rash[10]

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Pruritus: A disorder characterized by an intense itching sensation.[10]

Severity[10]*	In the MOTION trial[2]	
	Rate in ROMVIMZA-treated patients	Rate in placebo-treated patients
Grade 1: Mild or localized; topical intervention indicated	**Grade 1 or 2:** 26.6%	Grade 1 or 2: 8%
Grade 2: Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL		
Grade 3: Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated	2.4%	0%

Rash (maculo-papular): A disorder characterized by the presence of macules (flat) and papules (elevated). Also known as morbilliform rash, it is one of the most common cutaneous adverse events, frequently affecting the upper trunk, spreading centripetally, and associated with pruritus.[10†]

Severity[10]*	In the MOTION trial[2]	
	Rate in ROMVIMZA-treated patients	Rate in placebo-treated patients
Grade 1: Macules/papules covering <10% BSA with or without symptoms (e.g., pruritus, burning, tightness)	**Grade 1 or 2:** 26.6%	Grade 1 or 2: 5%
Grade 2: Macules/papules covering 10–30% BSA with or without symptoms (e.g., pruritus, burning, tightness); limiting instrumental ADL; rash covering >30% BSA with or without mild symptoms		
Grade 3: Macules/papules covering >30% BSA with moderate or severe symptoms; limiting self-care ADL	3.6%	0%

*Source: CTCAE Version 5.0 as was used in the MOTION trial.[2]
†The "Rash" in the AR table in the Prescribing Information grouped multiple related terms.[2]
BSA=body surface area.

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity:

- ROMVIMZA may cause fetal harm when administered to pregnant women. Advise pregnant women on the potential risk to the fetus.
- Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with ROMVIMZA and for 1 month after the last dose.

Please see additional Safety Information throughout.

General tips and suggestions for supportive care for pruritus and rash (maculo-papular)

Note: *These are general management tips and are not specific to ROMVIMZA, the MOTION study, or TGCT.*

- **Topical therapies (corticosteroid or cooling lotions with menthol or camphor)[14]:**
  May help reduce itching and inflammation
- **Using unscented products[14]:**
  Consider use of unscented lotions, ointments, and detergents; avoid irritating affected areas as they heal
- **Adding oatmeal or oil[14]:**
  Integrate into the bath early
- **Soap for only dirty areas[14]**
- **Shorten bath[14]**
- **Using a humidifier[14]:**
  Maintaining a humid environment could offer relief

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Allergic Reactions to FD&C Yellow No. 5 (Tartrazine) and No. 6 (Sunset Yellow FCF):

- ROMVIMZA 20 mg capsule contains FD&C Yellow No. 5 (tartrazine) which may cause allergic reactions (including bronchial asthma) in certain susceptible patients. FD&C Yellow No. 5 (tartrazine) sensitivity is frequently seen in patients who also have aspirin sensitivity.
- Advise patients that ROMVIMZA 14 mg and 20 mg capsules contain FD&C Yellow No. 6 (Sunset Yellow FCF), which may cause allergic reactions.

Increased Creatinine without Affecting Renal Function:

- Increases in serum creatinine can occur with the use of ROMVIMZA. These increases in serum creatinine may not be associated with changes in renal function. Increases in creatinine reversed upon ROMVIMZA discontinuation. During ROMVIMZA treatment, use alternative measures that are not based on serum creatinine to assess renal function.

Please see additional Safety Information throughout.

Important Safety Information for ROMVIMZA® (vimseltinib)

INDICATIONS AND USAGE

ROMVIMZA is indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hepatotoxicity:

- Cases of serious and fatal liver injury have occurred with the use of another kinase inhibitor that targets CSF1R. Serious and fatal liver injury have not been observed with ROMVIMZA.
- Elevated AST and ALT can occur with ROMVIMZA.
- Avoid ROMVIMZA in patients with pre-existing increased serum transaminases; total bilirubin or direct bilirubin (>ULN); or active liver or biliary tract disease, including ALP.
- Monitor liver function tests prior to initiation of ROMVIMZA, twice a month for the first two months and once every 3 months for the first year of therapy and as clinically indicated thereafter. Withhold and reduce the dose, or permanently discontinue ROMVIMZA based on the severity of the hepatotoxicity.

Embryo-Fetal Toxicity:

- ROMVIMZA may cause fetal harm when administered to pregnant women. Advise pregnant women on the potential risk to the fetus.
- Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with ROMVIMZA and for 1 month after the last dose.

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Increased Creatinine without Affecting Renal Function:

- Increases in serum creatinine can occur with the use of ROMVIMZA. These increases in serum creatinine may not be associated with changes in renal function. Increases in creatinine reversed upon ROMVIMZA discontinuation. During ROMVIMZA treatment, use alternative measures that are not based on serum creatinine to assess renal function.

Adverse Reactions:

The most common (≥20%) adverse reactions, including laboratory abnormalities that occurred in patients receiving ROMVIMZA were increased AST, periorbital edema, fatigue, rash, increased cholesterol, peripheral edema, face edema, decreased neutrophils, decreased leukocytes, pruritus, and increased ALT.

Drug Interactions:

- P-glycoprotein (P-gp) substrates: Avoid concomitant use of ROMVIMZA with P-gp substrates. If concomitant use cannot be avoided, take ROMVIMZA at least 4 hours prior to P-gp substrates.
- Breast Cancer Resistance Protein (BCRP) substrates: Avoid concomitant use of ROMVIMZA with BCRP substrates.
- Organic Cation Transporter 2 (OCT2) substrates: Avoid concomitant use of ROMVIMZA with OCT2 substrates.
- Concomitant use of vimseltinib with P-gp substrates, BCRP substrates or OCT2 substrates may increase exposure of these substrates.

Lactation: Advise females not to breastfeed during treatment with ROMVIMZA.

Please click for the full Prescribing Information.

References:

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma V.5.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed August 21, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **2.** ROMVIMZA [package insert]. Waltham, MA: Deciphera Pharmaceuticals, LLC. **3.** Gelderblom H, Bhadri V, Stacchiotti S, et al. Vimseltinib versus placebo for tenosynovial giant cell tumour (MOTION): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2024;403(10445):2709-2719. **4.** Gelderblom H, Bhadri V, Stacchiotti S, et al. Vimseltinib versus placebo for tenosynovial giant cell tumour (MOTION): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2024;403(10445)(suppl):1-124. **5.** Bauer S, Bhadri V, Gelderblom H, et al. Long-term efficacy and safety of vimseltinib in patients with tenosynovial giant cell tumor: 2-year results from the MOTION phase 3 trial. Poster presented at the European Society for Medical Oncology (ESMO) Congress 2025, October 17-21, Berlin, Germany. **6.** Stacchiotti S, Durr HR, Schaefer IM, et al. Best clinical management of tenosynovial giant cell tumour (TGCT): a consensus paper from a community of experts. *Cancer Treat Rev.* 2023;112:102491. **7.** Stacchiotti S, Durr HR, Schaefer IM, et al. Best clinical management of tenosynovial giant cell tumour (TGCT): a consensus paper from a community of experts. *Cancer Treat Rev.* 2023;112:102491(suppl):1-8. **8.** Bhadri V, Gelderblom H, Stacchiotti S, et al. Long-term clinical outcome assessments in patients with tenosynovial giant cell tumor treated with vimseltinib: 1-year results from the MOTION phase 3 trial. Poster presented at ASCO Annual Meeting, May 30–June 3, 2025, Chicago, IL, USA. **9.** Data on file. Deciphera Pharmaceuticals, LLC; 2026. **10.** National Cancer Institute. *Common Terminology Criteria for Adverse Events (CTCAE), Version 5.0*. US Dept of Health and Human Services; 2017. Accessed July 21, 2026. https://dctd.cancer.gov/research/ctep-trials/for-sites/adverse-events/ctcae-v5-5x7.pdf **11.** Edema. Cleveland Clinic. Updated February 4, 2026. Accessed July 21, 2026. https://my.clevelandclinic.org/health/diseases/12564-edema **12.** Side effect: swollen or puffy eyes (periorbital edema). ChemoExperts. Updated April 9, 2024. Accessed July 21, 2026. https://www.chemoexperts.com/swollen-or-puffy-eyes-periorbital-edema.html **13.** Edema (swelling) and cancer treatment. National Cancer Institute. Updated October 30, 2024. Accessed July 21, 2026. https://www.cancer.gov/about-cancer/treatment/side-effects/edema **14.** Pruritus (PDQ®)–Health Professional Version. National Cancer Institute. Updated January 17, 2025. Accessed July 21, 2026. https://www.cancer.gov/about-cancer/treatment/side-effects/skin-nail-changes/pruritus-hp-pdq

Romvimza® (vimseltinib) 30mg Capsules

In adults with symptomatic TGCT when surgery will potentially cause worsening functional limitation or severe morbidity[2]

Robust and durable tumor response[2] with ≥2 years of data available[5]*

- **40% ORR by RECIST with ROMVIMZA** vs 0% with placebo at 6 months[2]

Improvements in **active range of motion** and patient-reported improvements in **physical function† and worst pain[2]**

Well-characterized safety profile with ≥2 years of follow-up[2,5]

NCCN CATEGORY 1 PREFERRED

Vimseltinib (ROMVIMZA) is a Category 1 Preferred systemic therapy option for patients with TGCT[1]

Inform your patients they may be able to help advance TGCT research by taking part in a patient registry

*Median (range) treatment duration was 23.6 months (2–36) for patients randomized to ROMVIMZA and 19.1 months (1–30) for those who crossed over to ROMVIMZA.[5]

†Improved function is defined as an improvement in PROMIS-PF, which measures a patient's ability to do a range of daily activities.[3,4]

SELECT SAFETY INFORMATION

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The most common (≥20%) adverse reactions, including laboratory abnormalities that occurred in patients receiving ROMVIMZA were increased AST, periorbital edema, fatigue, rash, increased cholesterol, peripheral edema, face edema, decreased neutrophils, decreased leukocytes, pruritus, and increased ALT.

Please see additional Safety Information throughout and please click for the full Prescribing Information.

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