Romvimza™ (vimseltinib) 30mg Capsules

NCCN CATEGORY 1 PREFERRED

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

ROMVIMZA™ (vimseltinib) provides twice-weekly oral dosing with no known dietary restrictions[2]

TGCT=tenosynovial giant cell tumor; NCCN=National Comprehensive Cancer Network® (NCCN®).

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 click for the full Prescribing Information.

30 mg of ROMVIMZA
taken orally twice weekly

Romvimza™ (vimseltinib) 30mg Capsules

ROMVIMZA is for adult patients with tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.[2]



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

The recommended dosage of ROMVIMZA is 30 mg orally, taken twice weekly with a minimum of 72 hours between doses[2]

- ROMVIMZA may be taken with or without food[2]
- No clinically significant differences in pharmacokinetics were observed following administration of a high-fat meal[2]
- There are no known restrictions on consuming grapefruit or dairy products[2]

70% of patients in the MOTION study were on 30 mg at 6 months[3]



14 mg

Not actual size



20 mg

Not actual size



30 mg

Not actual size

4.8% (4 out of 83 patients) discontinued treatment due to adverse reactions.[2]

Adverse reactions or laboratory abnormalities led to[2]:

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

SELECT SAFETY INFORMATION

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.

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.

Recommended dose modifications

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For adverse reactions[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[2]

For hepatotoxicity[2]:

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 resolves 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 ≤3 times ULN or baseline. • Permanently discontinue if adverse reaction does not resolve within 4 weeks.
AST and/or ALT increases **>5–8 times ULN** **AND** total bilirubin increase **>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.

For P-glycoprotein (P-gp) substrates[2]:

Avoid concomitant use of ROMVIMZA with P-gp substrates. If concomitant use of a P-gp substrate is unavoidable, administer ROMVIMZA at least 4 hours before taking the P-gp substrate unless otherwise recommended in the substrate Prescribing Information.

SELECT SAFETY INFORMATION

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.

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decīphera AccessPoint™

Help your patients start ROMVIMZA with Deciphera AccessPoint

When enrolled, they get:

Insurance support:
Help with benefits investigations (BI) and navigating the prior authorization (PA), medical exceptions (ME), and appeals processes

Adherence support:
Nurse Advocates work with patients and care partners to understand and address their specific adherence challenges*

Free, temporary supply:
Patients may be eligible for a free, temporary supply if their insurance is delayed†

*Information and services provided by Deciphera AccessPoint are not intended to take the place of a healthcare provider. Nurse Advocates cannot provide medical or clinical advice.
†Terms and conditions apply. Not every patient is eligible.

Learn more about what ROMVIMZA offers with twice-weekly oral dosing and no known dietary restrictions[2] at ROMVIMZAHCP.com

SELECT SAFETY INFORMATION

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.5.2024. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed March 12, 2025. 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.

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