EMA/701116/2017
EMEA/H/C/006363

Romvimza (*vimseltinib*)

An overview of Romvimza and why it is authorised in the EU

What is Romvimza and what is it used for?

Romvimza is a medicine used to treat adults with symptomatic tenosynovial giant cell tumour (TGCT); it is used in people with TGCT who have serious movement limitations and for whom surgery is no longer an option or would cause serious long-term problems.

TGCT is a condition where a non-cancerous tumour develops around a joint and tendons and can damage surrounding tissues. It usually affects a single joint, most often the knee or ankle of young and middle-aged adults. Symptoms usually include pain, swelling, stiffness and difficulty moving the joint.

TGCT is rare, and Romvimza was designated an 'orphan medicine' (a medicine used in rare diseases) on 16 December 2019. Further information on the orphan designation can be found on the EMA website.

Romvimza contains the active substance vimseltinib.

How is Romvimza used?

Romvimza can only be obtained with a prescription, and treatment should be started by a healthcare professional experienced in the diagnosis and treatment of TGCT.

Romvimza is available as capsules to be taken by mouth twice a week. Treatment can continue as long as the patient benefits from it and does not have unacceptable side effects.

For more information about using Romvimza, see the package leaflet or contact your doctor or pharmacist.

How does Romvimza work?

TGCTs produce excessive amounts of a protein called CSF1. This protein attracts more cells and makes them multiply, making the tumour grow larger. The active substance in Romvimza, vimseltinib, blocks the activity of receptors (targets) for CSF1 on the cells. By reducing the effect of CSF1, the medicine is expected to slow growth of the tumour and therefore reduce symptoms of the disease.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Romvimza have been shown in studies?

A main study showed that Romvimza can reduce the size of the tumours in patients with TGCT. It involved 123 adults with TGCT who had symptoms, such as moderate to severe pain or joint stiffness, and for whom surgery would have caused serious problems. Patients received either Romvimza or placebo (a dummy treatment).

After 25 weeks of treatment, the tumour shrunk (partial response) in about 35% of patients who received Romvimza (29 out of 83), and was no longer detectable (complete response) in about 5% of those (4 out of 83). By 97 weeks of treatment with Romvimza, the proportion of patients with no detectable tumour increased to 23% (19 out of 83). This compares with none of those who received placebo. Additional data indicated that Romvimza can improve patients' movement and joint stiffness compared with placebo.

What are the risks associated with Romvimza?

For the full list of side effects and restrictions with Romvimza, see the package leaflet.

The most common side effects with Romvimza (which may affect more than 1 in 5 people) include increased levels of liver enzymes (which may indicate liver problems), periorbital oedema (swelling around the eyes), increased level of cholesterol, rash, increased level of creatinine (which may indicate kidney problems), decreased levels of neutrophils (a type of white blood cell), tiredness, oedema (swelling) of the face, pruritus (itching), peripheral oedema (swelling usually affecting the ankles and feet) and hypertension (high blood pressure).

Some side effects can be serious. These include peripheral oedema and increased levels of creatine phosphokinase (enzyme released into the blood when muscle is damaged), which may affect up to 1 in 100 people.

Romvimza must not be used during pregnancy.

Why is Romvimza authorised in the EU?

Romvimza has been shown to be effective at reducing the size of the tumours in adults with TGCT who have symptoms and cannot undergo surgery. In addition, it was noted that some patients treated with Romvimza reported improvements in their range of movement, as well as reduced joint stiffness and pain, indicating better quality of life. At the time of approval, patients with this rare disease had limited treatment options.

The side effects of Romvimza are considered acceptable. However, due to the limited safety data available, there is significant uncertainty about the medicine's long-term safety, especially regarding possible effects on the liver, kidneys and muscles as well as on blood pressure, brain or mental function and secondary tumours. To address this, the company will carry out a study to investigate Romvimza's long-term safety.

The European Medicines Agency decided that Romvimza's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Romvimza?

The company that markets Romvimza will provide materials to patients and healthcare professionals to warn them about the potential risk of harm to unborn babies. This warning is based on results from laboratory studies. Patients will receive a card reminding them that Romvimza must not be used during

pregnancy, and that people who can become pregnant should use effective contraception during treatment and up to one month after stopping treatment. Healthcare professionals will receive a guide with information on this risk, reminding them that people who can become pregnant should be adequately counselled before and during treatment, and a negative pregnancy test is required before starting treatment.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Romvimza have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Romvimza are continuously monitored. Suspected side effects reported with Romvimza are carefully evaluated and any necessary action taken to protect patients.

Other information about Romvimza

Romvimza received a marketing authorisation valid throughout the EU on 17 September 2025.

Further information on Romvimza can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/romvimza.

This overview was last updated in 09-2025.