Package leaflet: Information for the patient

ROMVIMZA 14 mg hard capsules
ROMVIMZA 20 mg hard capsules
ROMVIMZA 30 mg hard capsules

vimseltinib

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ROMVIMZA is and what it is used for
2. What you need to know before you take ROMVIMZA
3. How to take ROMVIMZA
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1. What ROMVIMZA is and what it is used for

ROMVIMZA contains the active substance vimseltinib, a kinase inhibitor.
It is used in adults to treat tenosynovial giant cell tumours (TGCTs) when it causes problems with physical function and when surgery may result in severe complications or disabilities.

TGCTs are rare tumours that affect the joints. Although these tumours are typically not cancerous, they are locally aggressive and can sometimes grow and cause damage to the joints and tissues around them. In very rare cases, TGCTs can change into cancerous (malignant) tumours.

The active substance in ROMVIMZA, vimseltinib, works by blocking the activity of certain proteins that are involved in the growth of TGCTs.

2. What you need to know before you take ROMVIMZA

Do not take ROMVIMZA if you are:
- allergic to vimseltinib or any of the other ingredients of this medicine (listed in section 6);
- pregnant (see section ‘Pregnancy and contraception’ for more information).

Warnings and precautions

Long-term safety
ROMVIMZA is a new medicine, and the long-term effects are still being studied. It may affect the liver, skin, brain, and other parts of the body.
Some side effects that have been reported include changes in blood tests, skin reactions and increase in blood pressure. There may also be a risk of memory problems, but there are uncertainties about this risk in the long-term.

Talk to your doctor, pharmacist or nurse before taking ROMVIMZA if:
- you have high blood pressure. Treatment with ROMVIMZA may increase blood pressure.
- you are, or plan to become, pregnant. The medicine may cause harm to your unborn baby. Women that can become pregnant must use effective birth control (contraception) during treatment with ROMVIMZA and for 30 days after the final dose. See 'Pregnancy and contraception' for more information.
- your kidneys or liver are not working properly. Your doctor will need to decide if this medicine is suitable for you. In clinical studies, treatment with ROMVIMZA often led to higher levels of a substance called creatinine, which may be a sign of kidney problems. However, there is not enough information yet to fully understand how this might affect your health.
- you have severe itching of the skin (pruritus). Your doctor may temporarily stop treatment or give you a lower dose of ROMVIMZA.
- you know you have high enzyme levels in your blood, or elevated bilirubin levels, or have liver or bile duct disease. Your doctor will need to decide if this medicine is suitable for you.

Regular blood tests
Before starting treatment with ROMVIMZA, your doctor will check your liver health through blood tests. These tests will be done once a month for the first two months, then once every three months during the first year of treatment. After that, tests will be done as needed based on your health condition. The blood tests ensure your liver health remains stable throughout your treatment. This monitoring helps detect any early signs of liver issues. Talk to your doctor, pharmacist or nurse if you have any concerns.

Children and adolescents
This medicine must not be given to children or adolescents under 18 years because there is no information about its use in this age group.

Other medicines and ROMVIMZA
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, vitamins and herbal supplements. This is because they may affect the way ROMVIMZA works or cause side effects.

Tell your doctor if you are taking any of the following medicines. Taking these medicines at the same time as ROMVIMZA may increase the concentrations of these medicines in your body, and increase the risk of side effects related to these medicines:
- rosuvastatin (used to lower cholesterol)
- metformin (used to treat type 2 diabetes by controlling blood sugar levels)
- dabigatran (a blood thinner used to treat and prevent blood clots, and prevent stroke in people with atrial fibrillation, a common heart rhythm problem)
- digoxin (used to treat heart rhythm problems and heart failure)

It is best not to take these medicines with ROMVIMZA. However, if your doctor advises that you must take these medicines, talk with your doctor about how best to take them.

Pregnancy and contraception
ROMVIMZA may cause harm to your unborn baby. If you are pregnant, think you may be pregnant or are planning to have a baby ask your doctor for advice before taking this medicine.

Do not take ROMVIMZA if you are pregnant. If you are a woman that can become pregnant, you must use effective contraception during treatment with ROMVIMZA and for 30 days after the final dose. If using hormonal contraception, add a barrier contraception (such as condoms).
If you are a woman that can become pregnant, you will be asked to take a pregnancy test before you start treatment with ROMVIMZA.

Fertility
In animal studies, this medicine has been shown to reduce sperm quality. It is not known whether this effect occurs in humans. Talk to your doctor if you have any concerns about fertility.

Breast-feeding
Do not breast-feed when taking ROMVIMZA. It is not known if this medicine passes into human milk, so there may be a risk to your breast-fed child.

Driving and using machines
ROMVIMZA has minor influence on your ability to drive or use machines. If you experience an extreme sense of tiredness and lack of energy or blurred vision, do not drive, use tools, or operate machines until you are feeling better.

ROMVIMZA 14 mg, 20 mg and 30 mg hard capsules contain lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

ROMVIMZA 14 mg hard capsules contain azo colouring agent sunset yellow FCF (E 110)
It may cause allergic reactions.

ROMVIMZA 20 mg hard capsules contain azo colouring agent sunset yellow FCF (E 110) and tartrazine (E 102)
They may cause allergic reactions.

3. How to take ROMVIMZA

Your treatment will be started by a doctor who is experienced in the treatment of conditions for which ROMVIMZA is indicated. Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is one 30 mg capsule, taken twice a week, at least 72 hours apart.

The capsules can be taken with or without food.
Swallow the capsules whole with a glass of water and do not open, break or chew the capsules. Do not take any capsules that are broken, cracked, or damaged. The effects of taking broken capsules are not known.

<u>Taking a lower dose</u>
- If you get intolerable side effects after a 30 mg dose, your doctor will temporarily stop the medicine. When your doctor is confident that you are better, you will be given a lower dose (20 mg).
- If you are instructed to take 20 mg, you should take one 20 mg capsule twice a week, at least 72 hours apart, with or without food.

- If you cannot tolerate the 20 mg dose, you will be given a 14 mg dose. You should take one 14 mg capsule twice a week, at least 72 hours apart, with or without food.
- If you cannot tolerate the lowest 14 mg dose or if your doctor considers it not adequate for your condition, ROMVIMZA treatment will be stopped completely.

If you take more ROMVIMZA than you should
If you, or someone else accidentally takes too many capsules, seek urgent medical attention and do not forget to take the medicine package and this leaflet with you.

If you forget to take ROMVIMZA
What to do if you forget to take this medicine will depend on when you realise that you missed a dose. If it is:
- less than 48 hours after the time you should have taken the medicine: take the missed dose as soon as you remember, then take the next dose as usual.
- more than 48 hours after the time you should have taken the medicine: skip the missed dose, then take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking ROMVIMZA
Do not stop taking this medicine without talking with your doctor first. It is important that you continue to take ROMVIMZA even if your symptoms improve and until the doctor decides to stop your treatment.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may occur with this medicine:

Very common (may affect more than 1 in 10 people):
- nerve damage (neuropathy), including nerve damage in the arms and legs, causing pain or numbness, burning and tingling; reduced sensation to touch, pain and temperature;
- swelling around the eye(s) (periorbital oedema), including eyelid(s);
- watery eye(s) (increased lacrimation);
- high blood pressure (hypertension);
- rash, including raised and/or flat reddened rash; itchy rash; small, raised, acne-like bumps; reddening of the skin;
- dry skin;
- itchy skin (pruritus);
- tiredness;
- swelling (oedema) of the face;
- swelling of the arms, legs or ankles (peripheral oedema);
- general swelling;
- abnormal blood test results that show high levels of creatine phosphokinase in your blood;
- abnormal blood test results that show high levels of liver enzymes in your blood;
- abnormal blood test results that show high levels of creatinine in your blood;
- abnormal blood test results that show that you have too much of a fatty substance called cholesterol in your blood;
- blood tests that show that you have low levels of white blood cells (neutrophils).

Common (may affect up to 1 in 10 people):
- dry eye;
- blurred vision.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ROMVIMZA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ROMVIMZA contains

ROMVIMZA 14 mg hard capsules
- The active substance is vimseltinib. Each hard capsule contains 14 mg of vimseltinib (as dihydrate).
- The other ingredients are:
  Capsule content: lactose monohydrate, crospovidone (E 1202) and magnesium stearate (E 470b). See section 2 ‘ROMVIMZA hard capsules contain lactose monohydrate’ for ingredients with known effects.
  Capsule shell: gelatin, titanium dioxide (E 171) and sunset yellow FCF (E 110). See section 2 ‘ROMVIMZA 14 mg hard capsules contain azo colouring agent sunset yellow FCF (E 110)’ for ingredients with known effects. Printing ink: shellac (E 904), propylene glycol (E 1520), potassium hydroxide (E 525), black iron oxide (E 172).

ROMVIMZA 20 mg hard capsules
- The active substance is vimseltinib. Each hard capsule contains 20 mg of vimseltinib (as dihydrate).
- The other ingredients are:
  Capsule content: lactose monohydrate, crospovidone (E 1202) and magnesium stearate (E 470b). See section 2 ‘ROMVIMZA hard capsules contain lactose monohydrate’ for ingredients with known effects.
  Capsule shell: gelatin, titanium dioxide (E 171), sunset yellow FCF (E 110) and tartrazine (E 102). See section 2 ‘ROMVIMZA 20 mg hard capsules contain azo colouring agent sunset yellow FCF (E 110) and tartrazine (E 102)’ for ingredients with known effects. Printing ink: shellac (E 904), propylene glycol (E 1520), potassium hydroxide (E 525), black iron oxide (E 172).

ROMVIMZA 30 mg hard capsules

- The active substance is vimseltinib. Each hard capsule contains 30 mg of vimseltinib (as dihydrate).
- The other ingredients are:
  Capsule content: lactose monohydrate, crospovidone (E 1202) and magnesium stearate (E 470b). See section 2 'ROMVIMZA hard capsules contain lactose monohydrate' for ingredients with known effects.
  Capsule shell: gelatin, titanium dioxide (E 171), brilliant blue FCF (E 133) and erythrosine (E 127). Printing ink: shellac (E 904), propylene glycol (E 1520), potassium hydroxide (E 525), black iron oxide (E 172).

What ROMVIMZA looks like and contents of the pack

ROMVIMZA 14 mg hard capsules
The hard capsule has an orange opaque cap and white opaque body. It is approximately 14 mm in length, imprinted with "DCV14" in black ink. The plastic and aluminium blister contains 8 capsules sealed in a cardboard wallet inside a carton, to cover four weeks of treatment.

ROMVIMZA 20 mg hard capsules
The hard capsule has a yellow opaque cap and white opaque body. It is approximately 18 mm in length, imprinted with "DCV20" in black ink. The plastic and aluminium blister contains 8 capsules sealed in a cardboard wallet inside a carton, to cover four weeks of treatment.

ROMVIMZA 30 mg hard capsules
The hard capsule has a light blue opaque cap and white opaque body. It is approximately 19 mm in length, imprinted with "DCV30" in black ink. The plastic and aluminium blister contains 8 capsules sealed in a cardboard wallet inside a carton, to cover four weeks of treatment.

Marketing Authorisation Holder and Manufacturer
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For any information about this medicine, please contact the Marketing Authorisation Holder.

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