

Package leaflet: Information for the patient

Mulpleo 3 mg film-coated tablets lusutrombopag

▼ 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, pharmacist, or nurse.
- 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Mulpleo is and what it is used for
2. What you need to know before you take Mulpleo
3. How to take Mulpleo
4. Possible side effects
5. How to store Mulpleo
6. Contents of the pack and other information

1. What Mulpleo is and what it is used for

Mulpleo contains the active substance lusutrombopag, which belongs to a group of medicines called thrombopoietin receptor agonists. The medicine helps to increase the number of *platelets* in your blood. Platelets are blood components that help the blood to clot and so prevent bleeding.

Mulpleo is used to **reduce the risk of bleeding during surgery and other procedures** (including tooth extractions and endoscopy). It is given to adults who have low numbers of platelets because of chronic liver disease.

2. What you need to know before you take Mulpleo

Do not take Mulpleo:

- **if you are allergic** to lusutrombopag or any of the other ingredients of this medicine (listed in section 6 under '*What Mulpleo contains*').
 - **Check with your doctor** if this applies to you before you take Mulpleo

Warnings and precautions

Talk to your doctor:

- **if you are at risk of blood clots** in your veins or arteries, or if you previously have had blood clots
- **if you have severe liver disease**
- **if your spleen has been removed**
- **if you are having interferon treatment.**

► **Talk to your doctor** before taking Mulpleo, if any of these applies.

Signs of a blood clot: look out for any of the signs below:

- **swelling, pain, heat, redness, or tenderness in your leg**

- **sudden shortness of breath**, especially with sharp pain in the chest or rapid breathing
- **pain in the abdomen** (tummy), swollen abdomen, blood in your stools.
 - ▶ **Get medical help immediately** if you notice any of these.

Children and adolescents

Do not give this medicine to children or adolescents under the age of 18 years, because the medicine has not been studied in children and adolescents.

Other medicines and Mulpleo

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

Do not take Mulpleo if you are pregnant unless your doctor specifically recommends it. The effect of Mulpleo during pregnancy is not known.

- **Tell your doctor** if you are pregnant, think you may be pregnant, or are planning to have a baby.
- **Use reliable methods of contraception** while you are taking Mulpleo.
- **If you do become pregnant** during treatment with Mulpleo, tell your doctor **immediately**.

Do not breast-feed during treatment with Mulpleo, as it is not known if the medicine passes into milk.

→ **If you are already breast-feeding**, talk to your doctor immediately.

Driving and using machines

Mulpleo has no known effects on your ability to drive or to use machines.

Mulpleo contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Mulpleo

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose: take one tablet once a day, at the same time each day, for seven days only. Take the tablet with a liquid and swallow it whole. Do not chew, break, or crush the tablet. You can take it with food or between meals.

Your treatment will start at least 8 days before your surgery or procedure. Do not change the dose or schedule for taking Mulpleo unless your doctor or pharmacist tells you to.

If you have severe liver disease, tell your doctor before taking Mulpleo.

If you take more than you should

If you have taken more Mulpleo than you should, talk to your doctor or go to the hospital. If possible, show them the pack, or this leaflet. You may be monitored for side effects associated with excessive platelets such as blood clots (see section 2, '*Warnings and precautions*', and section 4, '*Possible side effects*').

If you forget to take a tablet

If you miss a tablet of Mulpleo, take it as soon as you remember on the same day. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Mulpleo

Do not stop taking Mulpleo without talking to your doctor and do not take Mulpleo for more than 7 days.

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

4. Possible side effects

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

Higher risk of blood clots

Certain people may have a higher risk of blood clots, including people with liver disease, and medicines like Mulpleo could make this problem worse.

Signs of a blood clot: look out for any of the signs below:

- **swelling, pain, heat, redness,** or tenderness in **your leg**
- **sudden shortness of breath,** especially with sharp pain in the chest or rapid breathing
- **pain in the abdomen** (tummy), swollen abdomen, blood in your stools.

► **Get medical help immediately** if you notice any of these.

Common side effects

(may affect up to 1 in 10 people)

- Headache
- Nausea
- Blood clot in the liver (portal vein thrombosis)
- Rash.

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 Website: 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 Mulpleo

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 and blisters after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

This medicine does not require any special temperature storage conditions.

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 Mulpleo contains

- The active substance is lusutrombopag. Each film-coated tablet contains 3 mg lusutrombopag.
- The other ingredients are:
 - **Tablet core:** mannitol, microcrystalline cellulose, magnesium oxide, sodium lauryl sulfate, hydroxypropylcellulose, carmellose calcium and magnesium stearate
 - **Film coating:** hypromellose, titanium dioxide, triethyl citrate, talc and red-ferric oxide (E172)

What Mulpleo looks like and contents of the pack

Mulpleo 3 mg film-coated tablets are light red, 7 mm, round, film-coated tablets debossed with the Shionogi trademark above the identifier code “551” on one side and debossed with the strength “3” on the other side.

Mulpleo is supplied in aluminium blisters in a carton containing 7 film-coated tablets.

Marketing Authorisation Holder

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.