EMA/889817/2018
EMEA/H/C/004720

Lusutrombopag Shionogi (*lusutrombopag*)

An overview of Lusutrombopag Shionogi and why it is authorised in the EU

What is Lusutrombopag Shionogi and what is it used for?

Lusutrombopag Shionogi is a medicine used to prevent excessive bleeding in adults with thrombocytopenia due to long-standing liver disease. Patients with thrombocytopenia have reduced number of platelets (components in the blood that help it to clot), which can cause excessive bleeding.

The medicine is for use in patients having an invasive procedure (a medical procedure that involves cutting into or puncturing the skin or inserting instruments into the body).

Lusutrombopag Shionogi contains the active substance lusutrombopag.

How is Lusutrombopag Shionogi used?

Lusutrombopag Shionogi is available as 3-mg tablets. The medicine can only be obtained with a prescription.

Treatment with Lusutrombopag Shionogi should start at least 8 days before the procedure and the recommended dose is 1 tablet daily for 7 days.

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

How does Lusutrombopag Shionogi work?

In the body, a hormone called thrombopoietin stimulates the production of platelets by attaching to receptors (targets) in the bone marrow. The active substance in Lusutrombopag Shionogi, lusutrombopag, attaches to the same receptors as thrombopoietin, helping to increase the platelet count.

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What benefits of Lusutrombopag Shionogi have been shown in studies?

In two main studies involving adults with low levels of platelets due to long-standing liver disease, Lusutrombopag Shionogi increased platelet count before an invasive procedure and reduced the need for transfusions.

The first study, involving 96 adults, found that 79% of patients who took Lusutrombopag Shionogi did not require a transfusion of platelets before their procedure, compared with 13% of patients who received placebo (a dummy treatment). The second study involving 215 adults found that 65% of patients who took Lusutrombopag Shionogi did not require platelet transfusion before their procedure, compared with 29% of patients who received placebo.

What are the risks associated with Lusutrombopag Shionogi?

Unwanted effects that occurred in studies involving patients taking Lusutrombopag Shionogi were headache, nausea (feeling sick), portal vein thrombosis (a blockage in the blood vessel that carries blood from the intestines to the liver) and rash. Similar effects occurred in patients receiving placebo.

For more information on the side effects and restrictions of Lusutrombopag Shionogi, see the package leaflet.

Why is Lusutrombopag Shionogi authorised in the EU?

Studies have found that Lusutrombopag Shionogi increases platelet count, thereby lowering the risk of excessive bleeding during or after an invasive procedure and reducing the need for transfusing platelets. Unwanted effects that occurred in studies are thought to result from patients' medical condition and the nature of the invasive procedure for which Lusutrombopag Shionogi was used.

The European Medicines Agency decided that Lusutrombopag Shionogi'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 Lusutrombopag Shionogi?

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

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

Other information about Lusutrombopag Shionogi

Lusutrombopag Shionogi received a marketing authorisation valid throughout the EU on 18 February 2019.

Further information on Lusutrombopag Shionogi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/lusutrombopag-shionogi.

This overview was last updated in 03-2019.