EMA/628301/2019
EMEA/H/C/005012

Tavlesse (*fostamatinib*)

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

What is Tavlesse and what is it used for?

Tavlesse is a medicine for treating adults with chronic immune thrombocytopenia. It is for use when other treatments have not worked.

Chronic immune thrombocytopenia, previously called idiopathic thrombocytopenic purpura (ITP), is a long-term condition in which the immune system (the body's defences) destroys healthy platelets in the blood. Platelets are needed to form clots and stop bleeding. Patients with the disease have low platelet counts and may bruise or bleed easily.

Tavlesse contains the active substance fostamatinib.

How is Tavlesse used?

Tavlesse can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the treatment of blood diseases. It is available as tablets.

The recommended starting dose for Tavlesse is 100 mg twice daily and the doctor then adjusts the dose according to the patient's platelet count and the medicine's side effects. The maximum dose is 150 mg twice daily. Treatment is stopped after 12 weeks if the platelet count does not rise enough to prevent bleeding. The doctor may interrupt treatment or stop it permanently if certain side effects occur.

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

How does Tavlesse work?

Fostamatinib, the active substance in Tavlesse, blocks the activity of the enzyme spleen tyrosine kinase (SYK). This enzyme is involved in stimulating parts of the immune system. By blocking SYK's activity, fostamatinib reduces the immune system's destruction of platelets, so allowing the platelet count to rise, which reduces the likelihood of excessive bleeding.

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 Tavlesse have been shown in studies?

Tavlesse was found effective in two main studies involving a total of 150 patients with chronic immune thrombocytopenia. The platelet count was stable and above an acceptable level in 17% of patients taking Tavlesse for 24 weeks compared with 2% of patients receiving placebo (a dummy treatment).

What are the risks associated with Tavlesse?

The most common side effects with Tavlesse (which may affect more than 1 in 10 people) are dizziness, high blood pressure, frequent bowel movement and diarrhoea, nausea (feeling sick) and blood tests showing liver changes. Serious side effects (which may affect about 1 in 100 people) are febrile neutropenia (low white blood cell count with fever), diarrhoea, pneumonia (lung infection), and hypertensive crisis (dangerous rise in blood pressure).

Women must not take Tavlesse during pregnancy. For the full list of side effects and restrictions, see the package leaflet.

Why is Tavlesse authorised in the EU?

Tavlesse was found modestly effective for patients with immune thrombocytopenia when other treatments had not worked well enough and for whom there is no alternative treatment. Tavlesse can have serious side effects but they can be managed by taking precautions and reducing the dose. The European Medicines Agency therefore decided that Tavlesse'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 Tavlesse?

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

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

Other information about Tavlesse

Tavlesse received a marketing authorisation valid throughout the EU on 09 January 2020.

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

This overview was last updated in 12-2019.