EMA/243810/2019
EMEA/H/C/004722

Doptelet (*avatrombopag*)

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

What is Doptelet and what is it used for?

Doptelet 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).

Doptelet contains the active substance avatrombopag.

How is Doptelet used?

Doptelet can only be obtained with a prescription. It is available as 20-mg tablets.

Treatment with Doptelet should start at least 10 days before the procedure. The dose is 2 or 3 tablets (depending on the platelet count at the start of treatment), daily for 5 days. A blood test on the day of the procedure is necessary to ensure that the platelet count is adequate and not unexpectedly high.

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

How does Doptelet 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 Doptelet, avatrombopag, attaches to the same receptors as thrombopoietin, helping to increase the platelet count.

What benefits of Doptelet have been shown in studies?

Two main studies in 435 patients with low levels of platelets due to long-standing liver disease found Doptelet effective at increasing platelet levels before an invasive procedure. The main measure of effectiveness was the number of patients who did not require a transfusion of platelets or other treatment ('rescue procedure') to prevent excessive bleeding after starting Doptelet treatment and for up to 7 days after their invasive procedure.

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

In these studies, 88% of patients who received Doptelet 40 mg daily did not require a transfusion or rescue procedure compared with 36% of patients who were given placebo (a dummy treatment). Among patients with more severe thrombocytopenia, 67% of those given Doptelet 60 mg daily did not require a transfusion or rescue procedure compared with 29% of those who received placebo.

What are the risks associated with Doptelet?

The most common side effect with Doptelet (which may affect up to 1 in 10 people) is tiredness. For the full list of side effects and restrictions with Doptelet, see the package leaflet.

Why is Doptelet authorised in the EU?

Studies have found that Doptelet reduced the need for platelet transfusions or other rescue treatments to prevent excessive bleeding before an invasive procedure and for up to 7 days afterward. The platelet count increased in patients treated with Doptelet. Any unwanted effects during treatment with Doptelet were thought to result from patients' medical condition and the nature of the invasive procedure for which it was used.

The European Medicines Agency decided that Doptelet'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 Doptelet?

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

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

Other information about Doptelet

Doptelet received a marketing authorisation valid throughout the EU on 20 June 2019.

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

This overview was last updated in 06-2019.