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Revolade *(eltrombopag)*

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

What is Revolade and what is it used for?

Revolade is a medicine that is used for the treatment of:

- primary immune thrombocytopenia (ITP), a disease in which the patient's immune system destroys platelets (components in the blood that help it to clot). Patients with ITP have low platelet counts in the blood (thrombocytopenia) and are at risk of bleeding. Revolade is used in patients from 1 year of age for whom treatment with medicines such as corticosteroids or immunoglobulins has not worked. In children and adolescents, the medicine is used when they have had the disease for at least 6 months;
- thrombocytopenia in adults with chronic (long-term) hepatitis C, a liver disease caused by the hepatitis C virus. Revolade is used when the thrombocytopenia is too severe to allow interferon-based therapy (a type of treatment for hepatitis C);
- acquired severe aplastic anaemia (a disease in which the bone marrow does not make enough blood cells or platelets). Revolade is used in adult patients whose disease is not controlled by immunosuppressive therapy (medicines that lower the body's immune defences) and cannot receive haematopoietic stem cell transplantation (where the patient's bone marrow is replaced by stem cells from a donor to form new bone marrow).

Revolade contains the active substance eltrombopag.

How is Revolade used?

Revolade is available as tablets and as a powder to prepare a suspension (a liquid) to be taken by mouth. The medicine can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in treating blood diseases or chronic hepatitis C and its complications.

The dose depends on the patient's age and the disease for which Revolade is being used; it is adjusted as needed to maintain the appropriate platelet level.

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

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How does Revolade work?

In the body, a hormone called 'thrombopoietin' stimulates the production of platelets by attaching to certain receptors (targets) in the bone marrow. The active substance in Revolade, eltrombopag, also attaches to and stimulates the thrombopoietin receptors. This increases the production of platelets, improving platelet counts.

What benefits of Revolade have been shown in studies?

ITP in adults

For the treatment of ITP in adults, Revolade was compared with placebo (a dummy treatment) in two main studies involving a total of 311 patients who had previously been treated, but those treatments had not worked or the disease had come back.

Revolade was more effective than placebo: in the first study, 59% of the patients who took Revolade (43 out of 73) achieved a platelet count of at least 50,000 per microlitre (which is considered adequate to prevent bleeding complications) after 6 weeks of treatment, compared with 16% of those who took placebo (6 out of 37). In the second study, the 135 patients taking Revolade were around 8 times more likely to reach the target platelet count of between 50,000 and 400,000 per microlitre during the 6 months of treatment than the 62 patients who were given placebo.

A separate analysis of these data, in addition to data from another study, examined if the response to the medicine differed depending on when adult patients were diagnosed before they started treatment. In almost 400 patients with ITP, the number of patients who achieved a platelet count of at least 50,000 per microlitre after 6 weeks of treatment was generally comparable between patients diagnosed less than 6 months and those diagnosed more than 6 months before starting treatment. Data from scientific literature supported these findings.

ITP in children

In children with ITP, Revolade was more effective than placebo in one main study involving 92 children between 1 and 17 years of age who had previously been treated for ITP. This study lasted 13 weeks and looked at the proportion of patients whose platelet count had increased to at least 50,000 per microlitre for at least 6 out of 8 weeks, between week 5 to 12 of the study in the absence of rescue medication. This occurred in around 40% of those taking Revolade (25 out of 63) compared with around 3% (1 out of 29) of those who took placebo. An extension of the study found that Revolade was effective at maintaining adequate levels of platelets in the long term.

Thrombocytopenia associated with hepatitis C

For the treatment of thrombocytopenia associated with hepatitis C, two main studies involving a total of 1,441 adults were carried out. These compared Revolade with placebo for allowing the starting and maintenance of antiviral treatment in patients with hepatitis C whose platelet count was initially too low to allow starting such treatment (less than 75,000 per microlitre). In both studies, the main measure of effectiveness was the number of patients whose blood tests did not show any sign of hepatitis C virus 6 months after the end of treatment.

In these two studies, a higher proportion of patients who took Revolade tested negative for hepatitis C, compared with those who took placebo (23% versus 14% in the first study, and 19% versus 13% in the second study).

Severe aplastic anaemia

For the treatment of severe aplastic anaemia, Revolade was studied in 43 patients and was not compared with any other medicine. The main measure of effectiveness was the number of patients who responded to Revolade (whose platelet, red or white blood cell count remained above pre-set levels) after 12 or 16 weeks of treatment.

In this study, 40% of patients (17 out of 43) responded to treatment after 12 weeks, and in 65% of them (11 out of 17) the platelet count either increased by at least 20,000 per microliter or was stable without a need for blood transfusions. Preliminary data from a supportive study are consistent with the result of the main study, with 46% of patients responding to treatment after 12 weeks.

What are the risks associated with Revolade?

The most common side effects with Revolade in adults with ITP (which may affect more than 1 in 10 people) are nausea (feeling sick), diarrhoea and abnormal blood levels of certain liver enzymes. The most important serious side effects are liver problems and thromboembolic complications (problems with clots in blood vessels). In children with ITP, the most common side effects include nose and throat infection, cough, fever, pain in the belly or in the mouth and throat, toothache and runny nose.

In adults with severe aplastic anaemia the most common side effects include headache, dizziness, cough, pain in the belly or in the mouth and throat, nausea, diarrhoea, joint pain, pain in limbs, tiredness, fever and abnormal blood levels of certain liver enzymes.

In patients with thrombocytopenia and advanced chronic hepatitis C who are treated with interferon and Revolade, the most common side effects include headache, anaemia (low red blood cell counts), decreased appetite, cough, nausea, diarrhoea, high levels of bilirubin in the blood, hair loss, itching, muscle pain, fever, tiredness, flu-like illness, weakness, chills and swelling (because of build-up of water in the body). Important serious side effects are liver problems and thromboembolic complications.

For the full list of restrictions and side effects of Revolade, see the package leaflet.

Why is Revolade authorised in the EU?

The European Medicines Agency decided that Revolade'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 Revolade?

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

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

Other information about Revolade

Revolade received a marketing authorisation valid throughout the EU on 11 March 2010.

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

This overview was last updated in 10-2022.