EMA/326376/2018
EMEA/H/C/000480

Xagrid (*anagrelide*)

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

What is Xagrid and what is it used for?

Xagrid is a medicine used to reduce the number of platelets (components that help the blood to clot) in patients with essential thrombocythaemia (a disease in which there are too many platelets in the blood). 'Essential' means that the disease has no obvious cause.

Xagrid is used when patients do not respond to or do not tolerate their current treatment, and when they are 'at risk' because of their age (over 60 years), very high platelet counts or previous clotting problems.

Xagrid contains the active substance anagrelide.

How is Xagrid used?

Xagrid can only be obtained with a prescription. Treatment should only be started by a doctor who has experience in the treatment of essential thrombocythaemia.

Xagrid is available as capsules (0.5 mg). The recommended starting dose is 1 capsule twice a day. The dose can then be increased every week by 1 capsule a day, until the patient's platelet count is below 600 million platelets per millilitre, and ideally between 150 and 400 million/ml (the usual level in healthy people).

The maximum recommended dose of Xagrid is 5 capsules at a time. For more information about using Xagrid, see the package leaflet or contact a doctor or a pharmacist.

How does Xagrid work?

In essential thrombocythaemia the bone marrow produces too many platelets. The active substance in Xagrid, anagrelide, blocks the development and growth of cells in the bone marrow called 'megakaryocytes', which produce platelets. This reduces the platelet count, helping to improve symptoms in patients with the disease.

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What benefits of Xagrid have been shown in studies?

Xagrid was effective in lowering platelet counts in four main studies involving patients with various diseases in which the bone marrow produces too many cells. Almost 3,000 of the patients in the studies had essential thrombocythaemia, with a platelet count of more than 600 million/ml. Most patients had previously received other medicines but could not continue with them. Xagrid was not compared with any other medicines. Patients were treated with Xagrid for up to five years. The main measure of effectiveness was the number of patients who had a 'complete response', when platelet counts fell either by at least 50% from the start of treatment or to below 600 million/ml.

In the largest study, 67% of the patients with essential thrombocythaemia (628 out of 934), and 66% of those who could not tolerate other treatments or whose condition did not respond to them (480 out of 725) had a complete response to Xagrid. In the other three studies, between 60 and 82% of patients had a complete response.

What are the risks associated with Xagrid?

The most common side effect with Xagrid (which may affect more than 1 in 10 people) is headache. For the full list of all side effects of Xagrid, see the package leaflet.

Xagrid must not be used in patients with moderate or severe liver or kidney disease. For the full list of restrictions, see the package leaflet.

Why is Xagrid authorised in the EU?

The European Medicines Agency decided that Xagrid's benefits are greater than its risks and recommended that it be given marketing authorisation.

Xagrid was originally authorised under 'exceptional circumstances'. This is because, as a result of the disease's rarity, it had not been possible to obtain full information about it. As the company has supplied the additional information requested, the 'exceptional circumstances' ended on 11.07.2018.

What measures are being taken to ensure the safe and effective use of Xagrid?

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

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

Other information about Xagrid

Xagrid received a marketing authorisation valid throughout the EU on 16 November 2004.

Further information on Xagrid can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This summary was last updated in 06-2018.