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EPAR summary for the public

Anagrelide Mylan

anagrelide

This is a summary of the European public assessment report (EPAR) for Anagrelide Mylan. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Anagrelide Mylan.

For practical information about using Anagrelide Mylan, patients should read the package leaflet or contact their doctor or pharmacist.

What is Anagrelide Mylan and what is it used for?

Anagrelide Mylan 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 circulating in the blood). 'Essential' means that the disease has no obvious cause.

Anagrelide Mylan is used when the patient's current treatment does not work well enough or has unacceptable side effects, and when they are 'at risk' because of their age (over 60 years), very high platelet counts or previous clotting problems.

Anagrelide Mylan contains the active substance anagrelide and is a 'generic medicine'. This means that Anagrelide Mylan contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Xagrid. Anagrelide Mylan is also a 'hybrid medicine' because it is available in an additional strength. For more information on generic and hybrid medicines, see the question-and-answer document here.

How is Anagrelide Mylan used?

Anagrelide Mylan can only be obtained with a prescription. Treatment should only be started by a doctor who has experience in treating essential thrombocythaemia.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Anagrelide Mylan is available as capsules (0.5 and 1 mg). The recommended starting dose is one 0.5 mg capsule twice a day. After a week, the dose is increased every week by 0.5 mg a day, until the platelet count is below 600 million platelets per millilitre, and ideally between 150 and 400 million/ml (the level usually seen in healthy people). Results are normally seen within 2 or 3 weeks of starting treatment.

The maximum recommended dose of Anagrelide Mylan is 2.5 mg at a time.

How does Anagrelide Mylan work?

Essential thrombocythaemia is a disease in which the bone marrow produces too many platelets. This puts the patient at risk of developing blood clots or bleeding problems. The active substance in Anagrelide Mylan, 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.

How has Anagrelide Mylan been studied?

Studies on the benefits and risks of the active substance in the approved use have already been carried out with the reference medicine, Xagrid, and do not need to be repeated for Anagrelide Mylan.

As for every medicine, the company provided studies on the quality of Anagrelide Mylan. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Anagrelide Mylan?

Because Anagrelide Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Anagrelide Mylan approved?

The European Medicines Agency concluded that, in accordance with EU requirements, Anagrelide Mylan has been shown to have comparable quality and to be bioequivalent to Xagrid. Therefore, the Agency's view was that, as for Xagrid, the benefit outweighs the identified risk. The Agency recommended that Anagrelide Mylan be approved for use in the EU.

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

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

Other information about Anagrelide Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Anagrelide Mylan on 15 February 2018.

The full EPAR for Anagrelide Mylan can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about

treatment with Anagrelide Mylan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 02-2018.