14 December 2017
EMA/818102/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Anagrelide Mylan

anagrelide

On 14 December 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Anagrelide Mylan, intended for the reduction of elevated platelet counts in at risk essential thrombocythaemia patients. The applicant for this medicinal product is Mylan S.A.S.

Anagrelide Mylan will be available as 0.5 mg and 1 mg hard capsules. The active substance of Anagrelide Mylan is anagrelide, an antineoplastic agent (ATC code: L01XX35). The precise mechanism by which anagrelide reduces blood platelet count is unknown. Anagrelide is an inhibitor of cyclic AMP phosphodiesterase III.

Anagrelide Mylan is a generic and hybrid of Xagrid (0.5 mg hard capsules), which has been authorised in the EU since 16 November 2004. Studies have demonstrated the satisfactory quality of Anagrelide Mylan, and its bioequivalence to the reference product Xagrid. A question and answer document on generic medicines can be found here.

The full indication is:

"Anagrelide is indicated for the reduction of elevated platelet counts in at risk essential thrombocythaemia (ET) patients who are intolerant to their current therapy or whose elevated platelet counts are not reduced to an acceptable level by their current therapy.

An at risk patient

An at risk essential thrombocythaemia patient is defined by one or more of the following features:

- > 60 years of age or
- a platelet count > 1,000 x 10^9/l or
- a history of thrombo-haemorrhagic events."

It is proposed that Anagrelide Mylan be prescribed by a clinician with experience in the management of essential thrombocythaemia.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.