15 October 2020
EMA/CHMP/509778/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lenalidomide Mylan

lenalidomide

On 15 October 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lenalidomide Mylan, intended for the treatment of multiple myeloma and follicular lymphoma. The applicant for this medicinal product is Mylan Ireland Limited.

Lenalidomide Mylan will be available as hard capsules (2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg). The active substance of Lenalidomide Mylan is lenalidomide, an immunomodulating agent (ATC code: L04AX04) that works in a number of different ways including through cytokine modulation, induction of T-cell proliferation, anti-proliferation of multiple myeloma cells and inhibition of angiogenesis.

Lenalidomide Mylan is a generic of Revlimid, which has been authorised in the EU since 14 June 2007. Studies have demonstrated the satisfactory quality of Lenalidomide Mylan and its bioequivalence to the reference product Revlimid. A question and answer document on generic medicines can be found here.

The full indication is:

> Multiple myeloma
>
> Lenalidomide Mylan as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.
>
> Lenalidomide Mylan as combination therapy with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone (see section 4.2) is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.
>
> Lenalidomide Mylan in combination with dexamethasone is indicated for the treatment of multiple myeloma in adult patients who have received at least one prior therapy.
>
> Follicular lymphoma

[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

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

Lenalidomide Mylan in combination with rituximab (anti-CD20 antibody) is indicated for the treatment of adult patients with previously treated follicular lymphoma (Grade 1 – 3a).

Lenalidomide Mylan should be prescribed by physicians experienced in the use of cancer therapies.

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.