21 July 2022
EMA/CHMP/625361/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Thalidomide Lipomed

thalidomide

On 21 July 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Thalidomide Lipomed, intended for the treatment of multiple myeloma. The applicant for this medicinal product is Lipomed GmbH.

Thalidomide Lipomed will be available as a 100 mg coated tablet. The active substance of Thalidomide Lipomed is thalidomide, an immunosuppressant (ATC code: L04AX02), with immunomodulatory, anti-inflammatory and anti-neoplastic effects. These effects of thalidomide may be associated with the suppression of excessive tumour necrosis factor-alpha (TNF-alpha) production, down-modulation of selected cell surface adhesion molecules involved in leukocyte migration and anti-angiogenic activity.

The benefit of Thalidomide Lipomed, when used in combination with melphalan and prednisone, is its ability to provide a longer survival of newly diagnosed patients with multiple myeloma.

The most common side effects associated with the use of thalidomide in combination with melphalan and prednisone are neutropenia, leukopenia, constipation, somnolence, paraesthesia, peripheral neuropathy, anaemia, lymphopenia, thrombocytopenia, dizziness, dysaesthesia, tremor and peripheral oedema.

Thalidomide Lipomed is a hybrid medicine[2] of Thalidomide BMS (also previously known under the names Thalidomide Pharmion and Thalidomide Celgene) which has been authorised in the EU since 16 April 2008. Thalidomide Lipomed contains the same active substance as Thalidomide BMS, but it is presented as 100mg coated tablets, instead of 50mg hard capsules.

Studies have demonstrated the satisfactory quality of Thalidomide Lipomed, and its bioequivalence to the reference product Thalidomide BMS.

The full indication is:

[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
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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Thalidomide Lipomed in combination with melphalan and prednisone is indicated as first line treatment of patients with untreated multiple myeloma, aged ≥ 65 years or ineligible for high dose chemotherapy.

Thalidomide Lipomed should be prescribed by physicians with expertise in managing immunomodulatory or chemotherapeutic agents and a full understanding of the risks of thalidomide therapy and monitoring requirements. Thalidomide Lipomed should be prescribed and dispensed in accordance with the Thalidomide Lipomed Pregnancy Prevention Programme.

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.