13 December 2018
EMA/CHMP/825267/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Miglustat Dipharma

miglustat

On 13 December 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Miglustat Dipharma, intended for treatment of adult patients with mild to moderate type 1 Gaucher disease. The applicant for this medicinal product is Dipharma B.V.

Miglustat Dipharma will be available as capsules (100 mg). The active substance of Miglustat Dipharma is miglustat, an inhibitor of glucosylceramide synthase, the enzyme responsible for the first step in the synthesis of glycosphingolipids (ATC code: A16AX06). It works as substrate reduction therapy by reducing production of glycosphingolipids, the substrates of the defective enzyme in patients with type 1 Gaucher disease (glucocerebrosidase). Reducing glycosphingolipids levels is expected to slow down or prevent symptoms of type 1 Gaucher disease.

Miglustat Dipharma is a generic of Zavesca which has been authorised in the EU since 20 November 2002. Studies have demonstrated the satisfactory quality of Miglustat Dipharma, and its bioequivalence to the reference product Zavesca. A question and answer document on generic medicines can be found here.

The full indication is:

“Miglustat Dipharma is indicated for the oral treatment of adult patients with mild to moderate type 1 Gaucher disease. Miglustat Dipharma may be used only in the treatment of patients for whom enzyme replacement therapy is unsuitable”.

It is proposed that Miglustat Dipharma should be prescribed by physicians who are knowledgeable in the management of Gaucher disease.

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.

[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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact