



**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE  
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION\***  
**for**  
**ZAVESCA**

International Nonproprietary Name (INN): **miglustat**

On 18 December 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion\*\* to recommend the variation to the terms of the marketing authorisation for the medicinal product Zavesca. The Marketing Authorisation Holder for this medicinal product is Actelion Registration Ltd.

The CHMP adopted a new indication as follows: “*treatment of progressive neurological manifestations in adult patients and paediatric patients with Niemann-Pick type C disease*”.

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Zavesca will be as follows\*\*\*:

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

**Zavesca is indicated for the treatment of progressive neurological manifestations in adult patients and paediatric patients with Niemann-Pick type C disease”.**

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\* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

\*\* Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

\*\*\* The text in bold represents the new or the amended indication.