



17 March 2011
EMA/217136/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion¹ (post authorisation)

Xyrem

Sodium oxybate

On 17 March 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Xyrem. The marketing authorisation holder for this medicinal product is UCB Pharma Ltd. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new contraindication as follows:

- Patients with major depression

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), 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 contraindications for Xyrem will be as follows²:

- Hypersensitivity to the active substance or to any of the excipients.
- **Patients with major depression**
- Patients with succinic semialdehyde dehydrogenase deficiency.
- Patients being treated with opioids or barbiturates.

¹ 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.

² The text in bold represents the new or the amended contraindication.

