



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Benefits of sodium oxybate continue to outweigh risks in people with alcohol dependency

Studies required to further characterise efficacy

EMA's human medicines committee (CHMP) has concluded that the benefits of sodium oxybate syrup and oral solution (175 mg/ml) continue to outweigh their risks when used to treat acute alcohol withdrawal syndrome and to support long-term abstinence in people with alcohol dependency. However, due to limitations and uncertainties in the data, additional studies are required to further characterise the efficacy of the medicines in these uses.

The review was started at the request of the French medicines agency due to concerns about the efficacy of sodium oxybate in alcohol dependence, based on data from three studies.^{1,2,3} There were also concerns about the risk of abuse or misuse due to the medicine's psychoactive properties (effects on the brain), and whether the current measures to minimise these risks are adequate.

During the review, the CHMP considered the available evidence, including data from clinical studies, the scientific literature and post-marketing reports. The review found that the studies carried out after the medicines were authorised had methodological limitations, leading to uncertainties about the treatment effect. The Committee also noted that there have been advances in scientific and methodological standards since the studies supporting the initial authorisations were carried out. As a result, the CHMP has recommended that the companies should conduct new studies to further characterise the efficacy of the medicines. If this recommendation is confirmed by the European Commission, completion of these studies and submission of their study reports to national authorities will be a condition for maintaining the medicines' marketing authorisations.

In terms of safety, the medicines' safety profile remains consistent with what is already known. The review did not identify any new safety concerns regarding the risk of abuse or misuse with sodium oxybate in these indications and there was therefore no need to review existing additional risk minimisation measures.

¹ Nimmerrichter AA, Walter H, Gutierrez-Lobos KE, Lesch OM. Double-blind controlled trial of gamma-hydroxybutyrate and clomethiazole in the treatment of alcohol withdrawal. *Alcohol Alcohol*. 2002 Jan-Feb;37(1):67-73.

² Caputo F, Skala K, Mirijello A, Ferrulli A, Walter H, Lesch O, Addolorato G. Sodium oxybate in the treatment of alcohol withdrawal syndrome: a randomized double-blind comparative study versus oxazepam. The GATE 1 trial. *CNS Drugs*. 2014 Aug;28(8):743-52.

³ Guiraud J, Addolorato G, Antonelli M, et al. Sodium oxybate for the maintenance of abstinence in alcohol-dependent patients: An international, multicenter, randomized, double-blind, placebo-controlled trial. *J Psychopharmacol*. 2022 Oct;36(10):1136-1145.



The Committee concluded that the benefit-risk balance of sodium oxybate medicines in these indications remains favourable provided that the companies carry out the required studies to collect additional clinical data on the efficacy of the medicines.

The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

Information for patients

- In Austria and Italy, medicines containing sodium oxybate are used alone or as an add-on medicine, respectively, to treat acute alcohol withdrawal syndrome in adults with long-term alcohol abuse. In Austria, they are also used as add-on to support long-term abstinence in people with alcohol dependence.
- The medicines will continue to be available in Italy and Austria for these uses, but new studies will be carried out to collect more data on the effectiveness of the medicines.
- There are no new concerns about the safety of the medicines.
- If you are using a medicine containing sodium oxybate for acute alcohol withdrawal syndrome or to support long-term abstinence and you have questions about your treatment, speak to your doctor or pharmacist.

Information for healthcare professionals

- Post-authorisation studies of sodium oxybate medicines in acute alcohol withdrawal syndrome and long-term maintenance of abstinence have methodological limitations, leading to uncertainties about the treatment effect. There have also been advances in scientific and methodological standards since the studies supporting the initial authorisations were carried out.
- EMA has therefore recommended that the companies marketing these medicines conduct post-authorisation efficacy studies to better characterise the efficacy of these medicines in the treatment of acute alcohol withdrawal syndrome and long-term maintenance of abstinence.
- The medicines' safety profile remains consistent with what is already known. The review did not identify any new safety concerns regarding the risk of abuse or misuse with sodium oxybate.
- The benefit-risk balance of sodium oxybate medicines remains favourable provided the imposed studies are carried out.

More about the medicine

Sodium oxybate syrup and oral solution (175 mg/ml) is authorised nationally in Austria (since 1999) and Italy (since 1991) for use in alcohol-dependent patients, under the name Alcover. In Austria, it is available as a syrup for the treatment of acute alcohol withdrawal syndrome and as an adjuvant (add-on medicine) to support long-term abstinence under careful medical supervision as an adjuvant along with psychotherapy (counselling) and social rehabilitation. In Italy, it is available as an oral solution for use as an adjuvant to control acute alcohol withdrawal syndrome.

Sodium oxybate oral solution (500 mg/ml) is used to treat narcolepsy with cataplexy. The review does not include this medicine.

More about the procedure

The review of sodium oxybate syrup and oral solution (175 mg/ml) in the management of alcohol dependence was initiated at the request of the French medicines agency under [Article 31 of Directive 2001/83/EC](#).

The review has been carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which has adopted the Agency's opinion. The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.