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EMA starts review of sodium oxybate in alcohol dependence

Review will evaluate effectiveness in treating alcohol withdrawal syndrome and supporting abstinence, as well as measures to mitigate risk of abuse

EMA's human medicines committee (CHMP) has started a review of medicines containing sodium oxybate used in people with alcohol dependency to treat alcohol withdrawal syndrome and to support long-term abstinence.

The review was triggered by the assessment of a marketing authorisation application in France for a generic medicine containing sodium oxybate. During the assessment, the French medicines agency had concerns about the effectiveness 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.

Based on these data, EMA will now assess the overall benefit-risk balance of sodium oxybate to treat alcohol withdrawal syndrome and support long-term alcohol abstinence and will review measures to mitigate the risk of abuse or misuse. The Agency will then decide if any regulatory action should be taken.

More about the medicine

Medicines containing sodium oxybate (175 mg/ml) are used in adults with alcohol dependence on their own or as an add-on medicine to treat alcohol withdrawal syndrome and to support long-term abstinence under medical supervision, along with psychotherapy (counselling) and social rehabilitation.

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.



Sodium oxybate attaches to receptors (targets) on nerve cells of the brain and spinal cord for a substance called gamma-aminobutyric acid (GABA), leading to a calming of the activity of these cells. Since it targets these receptors in the same way as alcohol, sodium oxybate is used to treat the symptoms of alcohol withdrawal in alcohol-dependent patients, including agitation, tremor (shaking) and problems sleeping, and to support abstinence.

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

Sodium oxybate oral solution (500 mg/ml) is also used to treat narcolepsy. The review does not include these medicines.

More about the procedure

The review of sodium oxybate-containing medicines in the management of alcohol dependence has been initiated at the request of the French medicines agency under [Article 31 of Directive 2001/83/EC](#).

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