



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Selincro nalmefene

On 13 December 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Selincro, 18 mg*, film-coated tablet intended for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level, without physical withdrawal symptoms and who do not require immediate detoxification. The applicant for this medicinal product is H. Lundbeck A/S. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Selincro is nalmefene, a drug used in alcohol dependence. Nalmefene is an opioid system modulator with a distinct μ , δ , and κ receptor profile. It is a selective opioid receptor ligand with antagonist activity at the μ and δ receptors and partial agonist activity at the κ receptor. Acute alcohol intake was shown to result in mesolimbic dopamine release (facilitated by the release of β -endorphins), which can provide positive reinforcement. Nalmefene is thought to counteract the reinforcement effects and to reduce alcohol consumption, possibly by modulating these cortico-mesolimbic functions.

The benefits with Selincro are its ability to reduce alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level. The most common side effects are rather unspecific, such as nausea or dizziness. Some patients reported sleep-related events (either at day- or night-time).

A pharmacovigilance plan for Selincro will be implemented as part of the marketing authorisation.

The approved indication is: *Selincro is indicated for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (see section 5.1), without physical withdrawal symptoms and who do not require immediate detoxification.*

Selincro should only be prescribed in conjunction with continuous psychosocial support focussed on treatment adherence and reducing alcohol consumption.

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.

* Dosage corrected: 18.6 mg to 18 mg



Selincro should be initiated only in patients who continue to have a high drinking risk level two weeks after initial assessment.

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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Selincro and therefore recommends the granting of the marketing authorisation.