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EPAR summary for the public

Selincro

nalmefene

This is a summary of the European public assessment report (EPAR) for Selincro. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Selincro.

What is Selincro?

Selincro is medicine that contains the active substance nalmefene. It is available as tablets (18 mg).

What is Selincro used for?

Selincro is used to help reduce alcohol consumption in adults with alcohol dependence who consume more than 60 g of alcohol per day (for men) or more than 40 g per day (for women).

It should only be used together with psychosocial support (counselling) and only in people who do not have physical withdrawal symptoms and who do not require immediate detoxification.

As a guide: a bottle of wine (750 ml; 12% alcohol by volume) contains approximately 70 g alcohol and a bottle of beer (330 ml; 5% alcohol by volume) contains approximately 13 g alcohol.

Selincro can only be obtained by prescription.

How is Selincro used?

Before starting treatment with Selincro, the patient is asked to record their level of alcohol consumption over a two week period.

At the patient's initial visit to their doctor, the patient's overall health, alcohol dependence, and level of alcohol consumption (based on patient reporting) will be evaluated. Thereafter, the patient will be asked to record his or her alcohol consumption for approximately two weeks.

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At the next visit (after the two weeks), Selincro may be started if the patient continues to have a high level of alcohol consumption (above 60 g per day for men and 40 g per day for women).

Treatment must also include counselling to help the patient reduce their drinking and keep to their treatment.

The patient should take one Selincro tablet by mouth 'as needed', which means when there is a risk that they would start drinking. Only one tablet can be taken on any given day and it should preferably be taken one to two hours before they are likely to start drinking. If the patient has started drinking without Selincro, a tablet should be taken as soon as possible.

Data on the use of Selincro from standard clinical studies are available for a period of six months to one year. Caution is advised if Selincro is prescribed for more than one year.

How does Selincro work?

The active substance in Selincro, nalmefene, attaches to certain opioid receptors in the brain. Opioid receptors play a role in addiction and, by attaching to them and modifying their activity, nalmefene helps reduce the urge to drink in people accustomed to large amounts of alcohol.

Selincro does not prevent the intoxicating effects of alcohol.

How has Selincro been studied?

The effects of Selincro were first tested in experimental models before being studied in humans.

Selincro was compared with placebo (a dummy treatment) in two main studies involving 1,322 men and women with alcohol dependence. All patients also received counselling to help them reduce their drinking and keep to their treatment.

The main measures of effectiveness were the reduction in the number of heavy drinking days and the average daily alcohol consumption after six months of treatment.

What benefit has Selincro shown during the studies?

Selincro was shown to be more effective than placebo in reducing the number of heavy drinking days and daily alcohol consumption.

Significant improvements, usually observed within the first four weeks of treatment, were seen in patients who were already consuming more than 60 g of alcohol per day (for men) or more than 40 g of per day (for women). In these patients, after six months, the number of heavy drinking days a month with Selincro fell from 23 to 10 in the first study and from 23 to 11 in the second. Daily alcohol consumption with Selincro fell from 102 g to 44 g in the first study and from 113 g to 43 g in the second. These improvements were better than those seen with placebo by about 2.7 to 3.7 heavy drinking days a month and about 10 to 18 g of alcohol a day.

What is the risk associated with Selincro?

The most common side effects (seen in more than 1 patient in 10) were nausea (feeling sick), dizziness, insomnia (difficulty sleeping) and headache. The majority of these reactions were mild or moderate and of short duration.

Selincro must not be used in people who are hypersensitive (allergic) to nalmefene or any of its other ingredients. It must not be used in patients taking opioid medicines, in patients who have a current or

recent addiction to opioids, patients with acute opioid withdrawal symptoms, or in patients suspected to have used opioids recently.

It must also not be used in patients with severe liver or kidney impairment or a recent history of acute alcohol withdrawal syndrome (including hallucinations, seizures (fits) and tremors).

Why has Selincro been approved?

The CHMP noted that Selincro was shown to be effective in reducing alcohol consumption in men drinking more than 60 g and women drinking more than 40 g a day. With regard to safety, the side effects reported in the studies did not raise any major concerns. The CHMP decided that Selincro's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Selincro

The European Commission granted a marketing authorisation valid throughout the European Union for Selincro on 25 February 2013.

The full EPAR for Selincro can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Selincro, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2013.