

Package leaflet: Information for the patient

Selincro 18 mg film-coated tablets nalmefene

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Selincro is and what it is used for
2. What you need to know before you take Selincro
3. How to take Selincro
4. Possible side effects
5. How to store Selincro
6. Contents of the pack and other information

1. What Selincro is and what it is used for

Selincro contains the active substance nalmefene.

Selincro is used for the reduction of alcohol consumption in adult patients with alcohol dependence who still have a high level of alcohol consumption 2 weeks after the first consultation with their doctor.

Alcohol dependence occurs when a person has a physical or psychological dependence on the consumption of alcohol.

A high level of alcohol consumption is defined as drinking more than 60 g of pure alcohol per day for men and more than 40 g of pure alcohol per day for women. For example, 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.

Your doctor has prescribed Selincro because you were not able to reduce your alcohol consumption on your own. Your doctor will provide you with counselling to help you keep to your treatment and thereby reduce your alcohol consumption.

Selincro helps to reduce your alcohol consumption by affecting processes in the brain that are responsible for your urge to continue drinking.

A high level of alcohol consumption is associated with an increased risk of health and social problems. Selincro can help you reduce the amount of alcohol you drink, and keep the reduced level of alcohol consumption.

There is no risk of becoming dependent on Selincro.

2. What you need to know before you take Selincro

Do not take Selincro:

- if you are allergic to nalmefene or any of the other ingredients of this medicine (listed in section 6)
- if you are taking medicines containing opioids, for example, pain killers (such as morphine, oxycodone or other opioids)
- if you are or have recently been dependent on opioids. You may experience acute opioid withdrawal symptoms (such as feeling sick, vomiting, shakiness, sweating and anxiety)
- if you experience, or suspect you are experiencing opioid withdrawal symptoms
- if your liver or kidney function is poor
- if you are experiencing or have recently experienced several alcohol withdrawal symptoms (such as seeing, hearing or sensing things that are not there, seizures and shakiness)

Warnings and precautions

Talk to your doctor or pharmacist before taking Selincro. Inform your doctor about any other diseases you may have, for example, depression, seizure, liver or kidney disease.

If you and your doctor have decided that your immediate goal is abstinence (not drinking any alcohol), you should not take Selincro because Selincro is indicated for reduction of alcohol consumption.

If you require emergency medical attention, tell your doctor that you are taking Selincro. Your use of Selincro may affect your doctor's choice of emergency treatment.

If you are going to have a surgical procedure, talk to your doctor at least 1 week before the procedure. You may need to stop taking Selincro temporarily.

If you feel detached from yourself, see or hear things that are not there, and this continues to recur for more than a few days, stop taking Selincro and talk to your doctor.

If you are 65 years old or above, talk to your doctor or pharmacist before taking Selincro.

Children and adolescents

Selincro should not be used in children or adolescents below the age of 18 years because Selincro has not been tested in this age group.

Other medicines and Selincro

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Caution should be exercised when taking medicines such as diclofenac (antiinflammatory medicine used to treat, for

example, muscle pain), fluconazole (antibiotic used to treat diseases caused by some types of fungus), omeprazole (medicine used to block the production of acid in the stomach), or rifampicin (antibiotic used to treat diseases caused by some types of bacteria) together with Selincro.

If you take medicines containing opioids, the effects of these medicines will be reduced, or the medicines may not work at all if you take them together with Selincro. These medicines include certain types of cough and cold medicines, certain medicines for diarrhoea and strong pain killers.

Selincro with food and alcohol

Selincro does not prevent the intoxicating effects of alcohol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not known if Selincro is safe to use during pregnancy and breast-feeding.

Selincro is not recommended if you are pregnant.

If you are breast-feeding, you and your doctor should make a decision whether to discontinue breast-feeding or to discontinue Selincro therapy, taking into account the benefit of breast-feeding to the child and the benefit of therapy to you.

Driving and using machines

The effects of this medicine on the ability to drive and use machines have not been studied.

Selincro may cause side effects such as nausea, dizziness, insomnia, and headache. The majority of these reactions were mild or moderate, occurred at the beginning of treatment and lasted for a few hours to a few days. These side effects may affect your skills when driving or doing anything that requires you to be alert, including operating machinery.

Selincro contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Selincro

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

- The recommended dose is one tablet on days when you think there is a risk you will drink alcohol
- The maximum dose is one tablet per day.

How and when to take

- You should take the tablet 1-2 hours before you start drinking alcohol.

- Swallow the tablet whole, do not crush or divide the tablet.
- You can take Selincro with or without food.
- You can expect to be able to reduce your alcohol consumption within the first month after you start treatment with Selincro.
- Your doctor will follow up with you on a regular basis, for example, monthly after you start treatment with Selincro; the actual frequency will depend on your progress. Together you will decide how to continue.

If you take more Selincro than you should

If you believe you have taken too many Selincro tablets, contact your doctor or pharmacist.

If you forget to take Selincro

If you have started drinking alcohol without taking Selincro, take one tablet as soon as possible.

If you stop taking Selincro

After you stop treatment with Selincro, you may be less sensitive to the effects of medicines containing opioids for a few days.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Few cases of side effects of seeing, hearing or sensing things that are not there or feeling detached from oneself have been reported. However, the frequency of these side effects cannot be estimated from the available data.

The side effects reported with Selincro were mainly mild or moderate, occurred at the beginning of treatment and lasted for a few hours to a few days.

If you continue treatment with Selincro, or start again after a break in treatment, you will probably not have side effects.

In some cases, it may be difficult for you to distinguish side effects from the symptoms you may feel when you reduce your alcohol consumption.

The following side effects have been reported with Selincro:

Very common, which may affect more than 1 in 10 people:

- feeling sick
- dizziness
- inability to sleep
- headache

Common, which may affect up to 1 in 10 people:

- loss of appetite
- difficulty sleeping, confusion, feeling restless, reduced sex drive
- drowsiness, body twitches, feeling less alert, peculiar sensation in the skin like pins and needles, reduced sense of touch
- racing heart, a sensation of a rapid, forceful, or irregular beating of the heart
- vomiting, dry mouth

- excessive sweating
- muscle spasms
- feeling of exhaustion, weakness, discomfort or uneasiness, feeling strange
- weight loss

Other side effects:

- seeing, hearing or sensing things that are not there
- feeling detached from oneself

At this time, the frequency of these side effects cannot be estimated from the available data.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Alternatively you can call Freephone 0808 100 3352 (available between 10am-2pm Monday – Friday) or fill in a paper form available from your local pharmacy.

Ireland

FREEPOST

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

Malta

ADR Reporting

The Medicines Authority

Post-Licensing Directorate

203 Level 3, Rue D'Argens

G'ŻR-1368 Gzira

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt.

5. How to store Selincro

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (EXP) that is printed on the blister and carton. The expiry date refers to the last day of that month.
- Selincro does not require any special storage conditions.
- Do not use this medicine if you notice defects in the tablets, such as chipped or broken tablets.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Selincro contains

- Each film-coated tablet contains 18.06 milligram nalmefene (as hydrochloride dihydrate)
- The other ingredients are:
The tablet core: microcrystalline cellulose, anhydrous lactose, crospovidone (type A), magnesium stearate.
The film-coating of the tablet contains: hypromellose, macrogol 400, titanium dioxide (E171).

What Selincro looks like and contents of the pack

Selincro is a white, oval, biconvex, film-coated tablet of 6.0 x 8.75 mm. The tablet is engraved with 'S' on one side.

Selincro is available in packs containing 7, 14, 28, 42, 49 or 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

H. Lundbeck A/S
Ottiliavej 9
DK-2500 Valby
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Manufacturer

H. Lundbeck A/S
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu> .

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