Selincro

Notice: patient information

Selincro 18 mg film-coated tablets
nalmefene

Please 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. Do not give it to others. It may harm them, even if their signs of illness are the same as yours.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Que contient cette notice ?

1. WHAT IS SELINCRO AND WHAT IS IT USED FOR?
2. WHAT YOU NEED TO KNOW BEFORE TAKING SELINCRO?
3. HOW TO TAKE SELINCRO?
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE SELINCRO
6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

1. WHAT IS SELINCRO AND WHAT IS IT USED FOR?

Selincro contains the active substance nalmefene.

Selincro is used to reduce alcohol consumption in adult patients with alcohol dependence who maintain a high level of consumption 2 weeks after the first consultation with their doctor.

Alcohol addiction results in a physical or psychological dependence on alcohol.

Heavy alcohol consumption is defined as 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 of alcohol and a can of beer (330 mL; 5% alcohol by volume) contains approximately 13 g of alcohol.

Your doctor has prescribed Selincro because you have been unable to reduce your alcohol consumption on your own. Your doctor will provide advice to help you adhere to your treatment and therefore reduce your alcohol consumption.

Selincro acts on the brain, at the level of the areas responsible for your strong urge to continue drinking.

Heavy alcohol consumption is associated with an increased risk of health and social problems. Selincro can help you reduce your alcohol consumption and keep it lower.

2. WHAT YOU NEED TO KNOW BEFORE TAKING SELINCRO?

Never 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 medications containing opioids, such as methadone or buprenorphine or certain pain relievers (such as morphine, oxycodone or other opioids);
- if you are addicted or have recently been addicted to opioids. You may experience acute opioid withdrawal symptoms (such as nausea, vomiting, tremors, sweating, and anxiety);
- if you experience or think you may experience withdrawal symptoms;
- if your liver or kidneys are not functioning properly;
- if you are experiencing or have recently experienced several symptoms of alcohol withdrawal (such as seeing, hearing, or feeling things that are not there, seizures, or tremors).

Warnings and precautions

Talk to your doctor or pharmacist before taking Selincro. Tell your doctor about any other medical conditions you may have, such as depression, seizures, liver or kidney disease.

If you and your doctor have decided that abstinence (not drinking alcohol at all) is your immediate goal, you should not take Selincro because Selincro is used to reduce alcohol consumption.

If you need urgent medical attention, tell your doctor that you are taking Selincro. Your doctor will need to take your treatment with Selincro into account when choosing your emergency treatment.

If you are planning to have surgery, consult your doctor at least one week before the procedure. You may need to temporarily stop taking Selincro.

If you do not feel like yourself, if you see or hear things that are not there, and if this situation continues for several days, stop taking Selincro and talk to your doctor.

The risk of suicide, which is increased by alcohol and substance abuse, whether or not associated with depression, is not reduced by taking nalmefene.

If you are 65 years of age or older, tell your doctor or pharmacist before taking Selincro.

Children and adolescents

Selincro should not be used in children or adolescents under 18 years of age as Selincro has not been studied 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. Caution should be exercised if you are taking other medicines such as diclofenac (an anti-inflammatory medicine used, for example, to treat muscle pain), fluconazole (a medicine used to treat infections caused by certain types of fungi), omeprazole (a medicine used to block the production of acid in the stomach), or rifampicin (an antibiotic used to treat infections caused by certain types of bacteria) with Selincro.

If you take opioid medications while taking Selincro, the effects of these medications will be reduced, or these medications may not work at all. These medications include certain types of cough and cold medications, some antidiarrheals, and strong pain relievers.

Selincro with food and alcohol

Selincro does not prevent the intoxicating effects of alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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 taking Selincro is safe during pregnancy and breastfeeding.

Selincro is not recommended if you are pregnant.

If you are breastfeeding, you and your doctor should decide whether to discontinue breastfeeding or to discontinue treatment with Selincro, taking into account the benefit of breastfeeding for your child and the benefit of treatment for you.

Driving vehicles and using machines

Side effects such as disturbance in attention, visual disturbances, feeling abnormal, nausea, dizziness, drowsiness, insomnia, and headache may occur when starting treatment with Selincro. The majority of these effects were mild or moderate; they occurred at the beginning of treatment and lasted from a few hours to a few days. These side effects may affect your ability to drive or do any activity requiring alertness, including operating machinery.

Selincro contains lactose

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

3. HOW TO TAKE SELINCRO?

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

What dose to take

- The recommended dose is one tablet every day you feel the urge to drink alcohol.
- The maximum dose is one tablet per day.

How and when to take the medicine

- Selincro should be administered orally.
- You should take the medicine one to two hours before you start drinking alcohol.
- Swallow the tablet whole, do not crush or cut it as Selincro may cause a skin reaction when it comes into direct contact with the skin.
- You can take Selincro with or without food.
- You can expect to see your alcohol consumption decrease within the first month of starting treatment with Selincro.
- You will see your doctor regularly, for example every month after starting treatment with Selincro; the frequency will depend on your progress. Together you will decide how to continue.

If you take more Selincro than you should

If you think 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

You may be less sensitive to the effects of opioid medications for a few days after you stop taking Selincro.

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.

Side effects of seeing, hearing, or smelling things that are not there, or feeling like you are not yourself, are uncommon (may affect up to 1 in 100 people). If you experience any of these side effects, consult your doctor.

The side effects reported with Selincro are mostly mild or moderate. If they occur, they occur early in treatment and last from a few hours to a few days.
If you continue treatment with Selincro, or if you restart it after stopping it, you will probably not experience side effects.
In some cases, you may have difficulty distinguishing side effects from the symptoms you may experience when you reduce your alcohol consumption.

The following side effects have been reported with Selincro:

Very common (may affect more than 1 in 10 people)

- to feel sick
- feeling of dizziness
- inability to sleep
- headaches

Common (may affect up to 1 in 10 people)

- loss of appetite
- difficulty sleeping, confusion, feeling like you can't sit still, decreased libido
- drowsiness, tremors, decreased attention, strange sensations on the skin such as tingling, reduced sense of touch
- very fast heart rate, feeling of fast, pounding, or irregular heartbeats
- vomiting, dry mouth, diarrhea
- excessive sweating
- muscle contractions
- feeling tired, weak, unwell, feeling out of sorts
- weight loss.

Other adverse reactions (frequency cannot be estimated from the available data)

- visual disturbances (usually transient)
- swelling of the face, lips, tongue, or throat
- urticaria
- itching
- rash
- skin redness
- muscle pain
- prolonged erection (priapism)

Reporting of side effects
If you experience any side effects, talk to your doctor or pharmacist. 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.

Belgium:
Federal Agency for Medicines and Health Products
www.afmps.be
Vigilance Division:
Website: www.notifieruneffetindesirable.be
e-mail: adr@fagg-afmps.be

Luxembourg:
Regional Pharmacovigilance Centre of Nancy or Pharmacy and Medicines Division of the Health Directorate
Website: www.guichet.lu/pharmacovigilance

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 shown on the blister and packaging (EXP). The expiry date refers to the last day of that month.
- This medicine does not require any special storage measures.
- Do not take this medicine if you notice any defects in the tablets, such as chipped or broken tablets.
- Do not dispose of any medications via wastewater or household waste. Ask your pharmacist how to dispose of medications you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

What Selincro contains

- Each film-coated tablet contains 18.06 milligrams of nalmefene (as hydrochloride dihydrate).
- The other components are:

Tablet core: microcrystalline cellulose, anhydrous lactose, crospovidone (type A), magnesium stearate.
Tablet coating: hypromellose, macrogol 400, titanium dioxide (E171).

What Selincro looks like and contents of the pack
Selincro is a white, oval, biconvex, film-coated tablet, 6.0 x 8.75 mm.
The tablet is debossed with an 'S' on one side.

Selincro comes in boxes of 7, 14, 28, 42, 49 or 98 tablets in blister packs.

Not all presentations may be marketed.

Marketing Authorization Holder
H. Lundbeck A/S
Ottiliavej 9
DK-2500 Valby
Denmark

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

For any further information concerning this medicinal product, please contact the local representative of the marketing authorisation holder:

Belgium/Belgium/Belgien
Lundbeck SA/NV
Tel/Tel: +32 2 535 7979

Luxembourg/Luxemburg
Lundbeck SA
Tel/Tel: +32 2 535 7979

The last date this notice was revised is 01/2025.

Other sources of information

Detailed information on this medicine is available on the website of the European Medicines Agency https://www.ema.europa.eu .