

## **Patient leaflet in accordance with Pharmacist's Regulations (Preparations)**

**1986**

The medicine is marketed according to doctor's prescription only.

### **Selincro 18 mg film-coated tablets**

#### **Composition**

Each tablet of Selincro contains 18.06 mg nalmefene as hydrochloride dihydrate.

#### **Inactive ingredients**

See section 6.

- **Read the leaflet carefully until the end before using the medication.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or the pharmacist.
- This medicine was prescribed for you. Do not pass it on to others. It may harm them even if their medical condition seems similar to yours.
- The safety and efficacy of this medicine has not been tested in children and adolescents below age of 18 years therefore this medicine should not be used in this age group .

#### **1. What is the medicine for?**

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.

**Therapeutic group:** Modulator of the opioid system

## **2. Before using the medicine**

### **Do not use the medicine if:**

- if you are allergic to the active ingredient (nalmefene) or any of the other ingredients of this medicine (listed in section 6)
- if you are taking medicines containing opioids, for example, methadone or buprenorphine or 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)

### **Special warnings regarding the use of the medicine**

- Inform your doctor before taking Selincro 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.
  - The increased suicidal risk in alcohol and substances abusers, with or without accompanying depression, is not reduced by the intake of nalmefene.
  - If you are 65 years old or above, talk to your doctor 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**

**If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist.** It is especially important to inform the doctor or pharmacist if you are taking:

- 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)
- rifampicin (antibiotic used to treat diseases caused by some types of bacteria)
- 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.

### **Use of the medicine and food**

This medicine may be taken with or without food.

### **Use of the medicine and alcohol consumption**

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 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 breastfeeding 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**

Side effects such as disturbance in attention, visual impairment, feeling abnormal, nausea, dizziness, somnolence, insomnia and headache may occur when beginning Selincro treatment. 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.

### **Important information on some of the ingredients of the medicine.**

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 should you use the medicine?**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The dosage and treatment regimen will be determined by the doctor only.

The usual 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.

**Do not exceed the recommended dosage.**

- Selincro is for oral use.
- You should take the tablet 1-2 hours before you start drinking alcohol.
- Swallow the tablet whole, do not crush or divide the tablet because Selincro may cause skin sensitisation when in direct contact with the skin.
- 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 have accidentally taken a higher dosage** you should refer to a doctor: if a child has accidentally swallowed the medicine proceed immediately to a doctor or to the emergency room of the hospital and bring the package of the medicine with you.

- **If you have forgotten to take the medicine** – If you have started drinking alcohol without taking Selincro, take one tablet as soon as possible.

- You should complete the treatment recommended by the doctor. Even if an improvement in your state of health has begun, do not stop treatment with the medicine without consulting with a doctor.

- **If you stop taking the medicine** after you stop treatment with Selincro, you may be less sensitive to the effects of medicines containing opioids for a few days.

- Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

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

**4. Side effects**

As with all medicine, the use of Selincro may cause side effects in some users. Do not be alarmed at reading the list of side effects. You may not suffer from any of 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, diarrhoea, excessive sweating, muscle spasms, feeling of exhaustion, weakness, discomfort or uneasiness, feeling strange, weight loss.

Uncommon (may affect up to 1 in 100 people):

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

Other side effects (cannot be estimated from the available data):

visual impairment (mostly transient); swelling of face, lips, tongue or throat; hives; itching; rash; redness of skin; muscle pain; prolonged erection (priapism).

If you get a side effect, if one of the side effects worsens, or when you suffer from side effects not mentioned in this leaflet, consult with the doctor.

### **Reporting of side effects**

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site ([www.health.gov.il](http://www.health.gov.il)), which leads to an online form for reporting side effects.

Alternatively you can use the following link:

<https://sideeffects.health.gov.il/>

## **5. How should the medicine be stored?**

### **Avoid poisoning!**

This medicine and all other medicines should be stored in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning.

Do not induce vomiting unless explicitly instructed by a doctor to do so!

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.

- Storage conditions: store at a temperature lower than 30°C.

- 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 or expired. These measures will help protect the environment.

## **6. Additional information**

**In addition to the active ingredient the medicine also contains:**

microcrystalline cellulose, anhydrous lactose (60.68 mg), crospovidone (type A), magnesium stearate, hypromellose, macrogol 400, titanium dioxide (E171).

**- What does the medicine look like and contents of the pack:**

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, or 98 tablets. Not all pack sizes may be marketed.

**- Registration holder:** Lundbeck Israel Ltd., 11 Galgaley Haplada, P.O.B. 13105, Herzliya 4672211

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

Revised in July 2022 according to MoH guidelines.

Registration number of the medicine in the National Drug Register in the Ministry of Health: 151-35-33944

---