

## **Suboxone 2 mg/0.5 mg**

### **Sublingual tablets**

## **Suboxone 8 mg/2 mg**

### **Sublingual tablets**

#### **Active ingredients:**

Buprenorphine (as hydrochloride) 2 mg

Naloxone (as hydrochloride dihydrate) 0.5 mg

Buprenorphine (as hydrochloride) 8 mg

Naloxone (as hydrochloride dihydrate) 2 mg

**Inactive ingredients and allergens:** see section 6 "Further Information" and in section 2 "Important information regarding some of the ingredients of the medicine".

#### **Read this leaflet carefully in its entirety before using the medicine.**

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is intended for use in adults and adolescents over 15 years of age.

### **1. WHAT IS THE MEDICINE INTENDED FOR?**

Suboxone belongs to a group of medicines that act on the nervous system and are used to treat addiction disorders.

Suboxone is used to treat dependence on opioid preparations (narcotics), such as heroin or morphine, in drug addicts who have agreed to be treated for their addiction. Suboxone is used in adults and adolescents over 15 years of age, who are also receiving medicinal, social and psychological support.

#### **Therapeutic group:**

Buprenorphine - semi-synthetic opioid.

Naloxone - opioid agonist with antagonistic activity.

### **2. BEFORE USING THE MEDICINE**

#### **2.1 Do not use Suboxone if:**

- you are sensitive (allergic) to buprenorphine, naloxone (the active ingredients in Suboxone) or to any of the other ingredients in the medicine. For the list of inactive ingredients, see section 6.
- you have **serious breathing problems**.
- you have **serious problems with your liver**.
- you suffer from intoxication due to alcohol consumption or if you suffer from trembling, sweating, anxiety, confusion, or hallucinations caused by alcohol (delirium).
- you are taking naltrexone or nalmefene for the treatment of alcohol or opioid dependence.

#### **2.2 Special warnings regarding the use of Suboxone**

- An emergency unit should be contacted immediately in case of accidental ingestion or suspicion of ingestion.
- **Additional monitoring**  
You may be more closely monitored by your doctor if you are over the age of 65.
- **Misuse and abuse**  
This medicine can be a target for people who abuse prescription medicines. Keep the medicine in a safe place to protect it from theft (see in section 5 "How to store the medicine"). **Do not give this medicine to anyone else.** It can cause death or otherwise harm them.

- **Breathing problems**

Some people have died from respiratory failure (inability to breathe) because they misused buprenorphine or have taken it in combination with other central nervous system depressants, such as alcohol, benzodiazepines (tranquilizers) or other opioids.

This medicine may cause severe, possibly fatal, respiratory depression (reduced ability to breathe) in children and non-dependent people who accidentally or deliberately take it.

- **Sleep-related breathing disorders**

Suboxone can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

- **Dependence**

This medicine can cause dependence.

- **Withdrawal symptoms**

This medicine can cause opioid withdrawal symptoms if you take it too soon after taking an opioid. You should leave at least 6 hours after you use a short-acting opioid (e.g., morphine, heroin) or at least 24 hours after you use a long-acting opioid such as methadone.

Suboxone can cause withdrawal symptoms if you stopped taking it abruptly (see in section 3 “Stopping treatment”).

- **Liver damage**

Liver damage has been reported after taking Suboxone, especially if the medicine is misused. Liver damage can also be caused as a result of viral infections (e.g., chronic hepatitis C), alcohol abuse, anorexia or use of other medicines with the ability to harm your liver (see section 4 “Side effects”). **Your doctor may instruct you to have routine blood tests performed to monitor the condition of your liver. Before starting treatment with Suboxone, inform the doctor if you suffer from any liver problems.**

- **Blood pressure**

This medicine can cause a sudden drop in blood pressure and a dizzy feeling if you get up too quickly from sitting or lying down.

- **Diagnosis of unrelated medical conditions**

This medicine may mask pain symptoms that could assist in the diagnosis of certain diseases. Do not forget to inform the doctor that you are taking this medicine.

**Before treatment with Suboxone, tell the doctor if:**

- you suffer from asthma or breathing problems.
- you suffer from liver problems, such as hepatitis.
- you recently suffered from a head injury or brain disease.
- you suffer from low blood pressure.
- you suffer from a urinary system disorder (especially linked to enlarged prostate in men).
- you suffer from any kidney disease.
- you suffer from thyroid problems.
- you suffer from a disruption of the endocrine system (e.g., Addison's disease).
- you suffer from depression or other conditions that are treated with antidepressants. The use of these medicines together with Suboxone can lead to serotonin syndrome, a potentially life-threatening condition (see below “Drug interactions/reactions”).

## **2.3 Children and adolescents**

**Do not** give this medicine to **children under the age of 15**. If you are between 15 and 18 years old your doctor may monitor you more closely during treatment, because of the lack of data in this age group.

## **2.4 Drug interactions/reactions**

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

- **Benzodiazepines** (used to treat anxiety or sleep disorders) such as diazepam, temazepam, alprazolam. Concomitant use of Suboxone and sedative medicines such as benzodiazepines or similar drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma

and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor does prescribe Suboxone together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform your friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

- **Other medicines that may make you feel sleepy** which are used to treat illnesses such as anxiety, sleeplessness, convulsions/seizures, pain. These types of medicines may reduce your alertness levels making it difficult for you to drive or operate machines. They may also cause central nervous system depression, which is very serious.

Below is a list of examples of these types of medicines:

- Other opioid-containing medicines such as methadone, certain pain-killers and cough suppressants.
- Anti-depressants (used to treat depression) such as isocarboxazid, phenelzine, selegiline, tranylcypromine and valproate may increase the effects of this medicine.
- Sedative H<sub>1</sub> receptor antagonists (used to treat allergic reactions) such as diphenhydramine and chlorphenamine.
- Barbiturates (used to induce sleep or sedation) such as phenobarbital, secobarbital.
- Tranquilizers (used to induce sleep or sedation) such as chloral hydrate.
- **Anti-depressants** such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine or trimipramine. These medicines may interact with Suboxone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- Clonidine (used to treat high blood pressure), may extend the effect of this medicine.
- Anti-retroviral medicines (used to treat AIDS) such as ritonavir, nelfinavir, indinavir, may increase the effect of this medicine.
- Certain medicines for treatment of fungal infections, such as ketoconazole and itraconazole, certain antibiotics, may extend the effects of this medicine.
- Certain medicines may reduce the effect of Suboxone. These include medicines used to treat epilepsy (such as carbamazepine or phenytoin) and medicines used to treat tuberculosis (rifampicin).
- Naltrexone and nalmefene (medicines used to treat addictive disorders) may prevent the therapeutic effects of Suboxone. They should not be taken at the same time as Suboxone treatment because you may experience a sudden onset of prolonged and intense withdrawal.

To get the greatest benefit from taking Suboxone, you must inform your doctor about all the medicines you are taking, including alcohol, medicines containing alcohol, street drugs, and any prescription medicine you are taking that has not been prescribed to you by your doctor.

## **2.5 Use of Suboxone with food, beverage and alcohol**

**Do not drink alcohol** while being treated with this medicine. Alcohol may increase drowsiness and may increase the risk of respiratory failure if taken with Suboxone.

Do not swallow, eat or drink until the tablet has fully dissolved.

## **2.6 Pregnancy, breastfeeding and fertility**

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

The risks of using Suboxone during pregnancy are not known. Your doctor will decide if your treatment should be continued with an alternative medicine.

When taking Suboxone during pregnancy, particularly in late pregnancy, medicines like Suboxone may cause drug withdrawal symptoms, including problems with breathing in your newborn baby. This may appear several days after birth.

Do not breastfeed while taking Suboxone, since buprenorphine passes into breast milk.

In animal studies a reduction in female fertility was shown at high doses.

## **2.7 Driving and use of machinery**

**Do not** drive, ride a bicycle, use any tools or machines, or perform dangerous activities until you know how this medicine affects you. Suboxone may cause drowsiness, dizziness or impair your thinking. This may happen more often in the first few weeks of treatment when your dose is being changed, but it can also happen if you drink alcohol or take other sedative medicines at the same time as when you take Suboxone.

## **2.8 Important information regarding some of the ingredients of Suboxone**

Suboxone contains lactose. If you have been told by the doctor that you have an intolerance to some sugars, inform the doctor before taking the medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### 3. HOW SHOULD YOU USE SUBOXONE?

- The treatment is determined and monitored by doctors who are experienced in the treatment of drug dependence.
- Always use according to the doctor's instructions.
- The dosage and treatment regimen will be determined by the doctor only. During treatment, the doctor can adjust the dose depending upon your response. Check with the doctor if you are uncertain.
- Do not exceed the recommended dose.

#### Starting treatment

The recommended starting dosage for adults and adolescents over 15 years of age is 1-2 tablets of Suboxone 2 mg/0.5 mg. An additional 1-2 tablets of Suboxone 2 mg/0.5 mg may be administered on the first day depending on the need.

Clear signs of withdrawal should be evident before taking your first dose of Suboxone.

The doctor's assessment of your readiness for treatment will guide him in determining the timing of your first Suboxone dose.

- Starting treatment with Suboxone while dependent upon heroin

If you are addicted to heroin or a short-acting opiate, the first dose of Suboxone should be taken when signs of withdrawal appear, but no less than 6 hours after the last use of heroin.

- Starting treatment with Suboxone while dependent upon methadone

If you are taking methadone or a long-acting opiate, the dosage of methadone should be reduced to below 30 mg/day before beginning Suboxone therapy. The first dose of Suboxone should be taken when signs of withdrawal appear, but no less than 24 hours after the last use of methadone.

- Duration of treatment

The duration of treatment will be individually determined by you and your doctor.

#### How to use

- Take the dose once a day by holding the tablet under your tongue.
- Keep the tablet under your tongue until it has **fully dissolved**. This may take 5-10 minutes. Do not crush or divide the tablet.
- Suboxone should be taken whole. Do not halve, chew, crush or swallow the tablets, as the medicine will not work and you may get withdrawal symptoms. While Suboxone dissolves, do not chew or swallow the tablet since the medicine will not work as well.
- Do not eat or drink until the tablets have fully dissolved.

#### Dosage adjustment and maintenance therapy

During the days after the initiation of treatment, the doctor can increase the dosage of Suboxone, according to your needs. If you have the impression that the effect of Suboxone is too strong or too weak, refer to the doctor.

The maximum daily dosage is 24 mg (namely, 3 Suboxone 8 mg/2 mg tablets, when the patient is stabilized in treatment).

After a period of successful treatment, your doctor may decide to gradually reduce the dosage to a lower maintenance dosage.

#### Stopping treatment

Depending on your condition, the dosage of Suboxone may continue to be reduced under close medical supervision, until it is eventually terminated.

Do not change the treatment in any way or stop treatment without the agreement of your attending doctor.

- **If you accidentally take a higher dose**

If you took an overdose or if a child has accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of the medicine with you, to receive treatment for Suboxone **overdose** that may cause severe and life-threatening breathing problems.

Signs of overdose can include feeling drowsy, difficulty coordinating actions with slowed reflexes, blurred vision and/or slurred speech. You may be unable to think clearly and may breathe more slowly than is normal for you.

- **If you forget to take Suboxone**

Contact the doctor as soon as possible.

- **If you stop using Suboxone**

Do not change or stop the treatment in any way without the agreement of your attending doctor. **Sudden**

discontinuation of treatment may cause withdrawal symptoms.

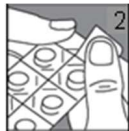
**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.**

**How to remove the tablet from the blister:**



1 – Do not push the tablet through the foil



2 – Remove just one section from the blister pack, by tearing it along the perforated line.



3 – Starting from the edge where the seal is lifted, pull back the aluminum foil on the back to remove the tablet.

If the blister is damaged, discard the tablet.

#### **4. SIDE EFFECTS**

As with any medicine, use of Suboxone may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Refer to the doctor immediately or seek urgent medical attention** if you experience side effects, such as:

- swelling of the face, lips, tongue or throat, which may cause difficulty in swallowing or breathing, severe hives/rash. These may be signs of a life-threatening allergic reaction.
- feeling sleepy and uncoordinated, blurred vision, slurred speech, inability to think well or clearly or breathing more slowly than is normal for you.

**Also tell your doctor immediately** if you experience side effects such as:

- severe tiredness, itching with yellowing of the skin or eyes. These may be symptoms of liver damage.
- seeing or hearing things that are not there (hallucinations).

#### **Additional side effects**

<b><i>Very common side effects (may affect more than 1 in 10 users):</i></b>
Insomnia (inability to sleep), nausea, constipation, excessive sweating, headache, drug withdrawal syndrome.
<b><i>Common side effects (may affect up to 1 in 10 users):</i></b>
Weight loss, swelling of the hands and feet, drowsiness, anxiety, nervousness, tingling, depression, decreased sexual desire, increase in muscle tension, abnormal thinking, increased tearing (watering eyes) or other tearing disorders, blurred vision, flushing, increased blood pressure, migraines, runny nose, sore throat and painful swallowing, increased cough, upset stomach or other stomach discomfort, diarrhea, abnormal liver function, flatulence, vomiting, rash, itching, hives, pain, joint pain, muscle pain, leg cramps (muscle spasms), difficulty in getting or keeping an erection, urine abnormality, abdominal pain, back pain, weakness, infection, chills, chest pain, fever, flu-like symptoms, feeling of general discomfort, accidental injury caused by loss of alertness or coordination, faintness and dizziness.
<b><i>Uncommon side effects (may affect up to 1 in 100 users):</i></b>
Swollen glands (lymph nodes), agitation, tremor, abnormal dreams, excessive muscle activity, depersonalization (not feeling like yourself), medicine dependence, amnesia (memory disturbance), loss of interest, exaggerated feeling of well-being, convulsions (fits), speech disorder, small pupil size, difficulty passing urine, eye inflammation or infection, rapid or slow heartbeat, low blood pressure,

palpitations, heart attack, chest tightness, shortness of breath, asthma, yawning, pain and sores in mouth, tongue discoloration, acne, skin nodules, hair loss, dry or scaling skin, inflammation of joints, urinary tract infection, abnormal blood tests, blood in urine, abnormal ejaculation, menstrual or vaginal problems, kidney stones, protein in your urine, painful or difficult urination, sensitivity to heat or cold, heat stroke, loss of appetite, feelings of hostility.

**Side effects of unknown frequency** (frequency can not be estimated from the available data):

Sudden withdrawal syndrome caused by taking Suboxone too soon after use of illicit opioids, drug withdrawal syndrome in newborn babies, slow or difficult breathing, liver injury with or without jaundice, hallucinations, swelling of face and throat or life threatening allergic reactions, drop in blood pressure on changing position from sitting or lying down to standing.

Misusing this medicine by injecting it can cause withdrawal symptoms, infections, other skin reactions and potentially serious liver problems (see in section 2 "Special warnings regarding use of Suboxone").

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects following drug treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

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

## 5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of other household members, children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use Suboxone after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store the medicine in a safe place. Buprenorphine may cause severe, possible fatal, respiratory depression (reduced ability to breath), possible fatal, in children and non-dependent people who accidentally or deliberately take it.
- Suboxone can be a target for people who abuse prescription medicine. Keep this medicine in a safe place to protect it from theft.
- Store the blister safely.
- Never open the blister in advance.
- Do not take the medicine in front of children.
- An emergency unit should be contacted immediately in case of accidental ingestion or suspicion of ingestion.
- **Storage conditions:** Store below 30°C.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:  
lactose monohydrate, mannitol, maize starch, natural lemon and lime flavour, povidone K30, citric acid anhydrous granular, magnesium stearate, acesulfame potassium, sodium citrate.

### • What the Suboxone tablets look like and the contents of the package

Suboxone 2 mg/0.5 mg sublingual tablets are white, hexagonal, biconvex tablets of 6.5 mm, with "N2" debossed on one side.

Suboxone 8 mg/2 mg sublingual tablets are white, hexagonal, biconvex tablets of 11 mm, with "N8" debossed on one side.

The tablets are provided in packs of 7 and 28 tablets.

Not all pack sizes may be marketed.

**Manufacturer and address:** Indivior UK Limited, Slough, Berkshire, UK.

**License holder and address:** Naomi Shaco-Ezra Ltd., P.O.B 6825, Ramat Gan 52167.

Revised in November 2021 according to MOHs guidelines.

### • Registration number of the medicine in the National Drug Registry of the Ministry of Health:

**Suboxone 2 mg/0.5 mg: 149 56 33732**

**Suboxone 8 mg/2 mg: 149 57 33733**