

# Prefibin 2 mg Sublingual Tablets

# Prefibin 8 mg Sublingual Tablets

## buprenorphine

**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.

### What is in this leaflet:

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



## 1 What Prefibin is and what it is used for

Prefibin is used to treat

- **opioid dependence**

Prefibin is part of a medical, social and psychological treatment programme for patients addicted to opiate (narcotic) drugs. Treatment is prescribed and monitored by doctors who are specialists in the treatment of drug dependence. Treatment with Prefibin is intended for use in adults and adolescents aged 15 years and over.

## 2 What you need to know before you take Prefibin

### Do not take Prefibin

if you are/have

- allergic to:
  - buprenorphine or any of the other ingredients of this medicine (listed in section 6)
- serious breathing problems
- serious liver problems
- intoxicated due to alcohol or have trembling, sweating, anxiety, confusion or hallucinations caused by alcohol
- under 15 years of age
- breast-feeding a baby

### Warnings and precautions

Talk to your doctor or pharmacist before taking Prefibin if any of the following apply to you:

- breathing problems such as asthma  
You must not use Prefibin if you have serious breathing problems.
- recent head injury or brain disease
- have had fits (seizures)
- reduced kidney function
- reduced liver function  
Acute liver problems have been reported which could be due to:
  - misuse, especially through administration into a vein and at a high dose
  - previous existing liver problems
  - viral infections, such as hepatitis B or hepatitis C
  - alcohol abuse
  - anorexia
  - liver damaging medicines.
 Inform your doctor immediately if you experience symptoms of liver problem such as severe fatigue, itching and yellow skin or eyes. You can then receive the proper treatment. However, you must not use Prefibin if you have a serious liver disease.
- certain heart rhythm conditions (long QT syndrome or prolonged QT interval)
- low blood pressure
- urinary disorders, especially due to enlarged prostate in men
- thyroid problems
- disorder of the kidney cortex (e.g. Addison's disease)
- bile problems
- depression or other conditions that are treated with antidepressants  
The use of these medicines together with Prefibin can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Prefibin").
- you are below 18 years or over 65 years old.

In general, all patients have to undergo a liver test prior to Prefibin therapy and your doctor may monitor your liver function regularly during treatment.

This medicine may mask pain of other diseases. Advise your doctor that you are taking this medicine.

### Sleep-related breathing disorders

Prefibin 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.

### Misuse, abuse and diversion

Serious cases of infections with potential fatal outcome may occur in a context of misuse of Prefibin, when administered by the intravenous route.

Some users died from breathing failure after misusing buprenorphine or combining it with brain acting substances, such as:

- alcohol
- medicines which calm, induce sleep or relax muscles with active substance names ending with "azepam", such as diazepam, temazepam
- other opioids

If it is not possible for you to stop misuse, please talk to your doctor, who will provide advice on adequate treatment for problems like depression, anxiety or difficulty in sleeping.

This medicine can cause withdrawal symptoms if you take it

- less than 6 hours after using a short acting opioid, such as morphine, heroin.
- or less than 24 hours after you use a long acting opioid such as methadone.

This medicine can cause dependence.

This medicine can be a target for people who abuse prescription medicines, and should be kept in a safe place to protect it from theft. Do not give this medicine to anyone else. It can cause death or otherwise harm them. A dose suitable for you may be deadly for another person.

### Effects of misuse for doping

Athletes should be aware that this medicine may cause a positive reaction to sports doping control

tests. Use of Prefibin as a doping agent may become a health hazard.

### Children and adolescents

Do not give this medicine to children below the age of 15 years, since efficacy and safety of buprenorphine in this age group have not been proven.

### Other medicines and Prefibin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines can affect or be affected by Prefibin:

- **medicines which calm, induce sleep or relax muscles** with active substance names ending with "azepam", such as diazepam, temazepam (named benzodiazepines): Concomitant use of Prefibin and sedative medicines such as benzodiazepines or related medicines 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 Prefibin 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 friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.  
Do not take these medicines while taking Prefibin where risk of misuse exists.
- **gabapentinoids (gabapentin or pregabalin)** (used to treat epilepsy or neuropathic pain): concomitant use may increase the risk of life-threatening breathing difficulties and death, because both medicines can contribute to very slow and shallow breathing (respiratory depression). Therefore, only take gabapentinoids when using Prefibin if explicitly recommended by your doctor and do not exceed the dose that your doctor has prescribed for you.
- **medicines to treat epilepsy or to sedate**, with active substance names mostly ending with "tal", such as phenobarbital
- **other medicines used to treat anxiety or sleep disorders**
- other **strong painkillers** or medicines to treat cough, such as codeine, dihydrocodeine, morphine
- **methadone**, a medicine to treat severe pain, or to counter addiction
- **naltrexone**, a medicine to counter alcohol or opiate drug addiction
- certain medicines to treat depression or Parkinson's disease known as **monoamine oxidase inhibitors**, such as moclobemide
- other medicines to treat depression
- certain antidepressants (used to treat depression) such as isocarboxazide, phenelzine, selegeline, tranylcypromine and valproate
- **anti-depressants** such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine.  
These medicines may interact with Prefibin 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.
- **medicines to treat allergies**, sleep disturbances or cold; or prevent and treat nausea and vomiting; such as doxylamine, diphenhydramine
- **medicines to treat mental or anxiety disorders**, with sedative effects, such as chlorpromazine, haloperidol
- certain medicines to treat high blood pressure, such as **clonidine**
- Your doctor may prescribe you a lower

Prefibin dose if you take any of the following medicines:

- **ketoconazole, itraconazole**: medicines to treat fungal infections
- certain antibiotics (macrolides) to treat bacterial infections, such as clarithromycin, erythromycin
- medicines to treat **HIV infections**, such as ritonavir, nelfinavir, indinavir.
- Your doctor may supervise you closely if you take any of the following medicines:
  - **medicines to treat epilepsy**, such as phenobarbital, carbamazepine, phenytoin
  - **rifampicin**: a medicine to treat bacterial infections

If you need the help of a doctor or a hospital, you must provide information on your substitution therapy and also be honest relating to your actual consumption of other medicines or drugs. This is necessary to avoid dangerous combinations.

### Prefibin with food, drink and alcohol

Alcohol may increase drowsiness and may increase the risk of respiratory failure (inability to breathe) if taken with Prefibin. Do not drink alcohol or take any medicines that contain alcohol while taking Prefibin. Do not swallow or consume food or drink until the tablet is completely dissolved.

### 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.

• **Pregnancy**

When taken during pregnancy, particularly late pregnancy, medicines like Prefibin may cause drug withdrawal symptoms and breathing problems in your newborn baby. These symptoms may occur several days after birth. Only use Prefibin during pregnancy if specifically recommended by your doctor.

• **Breast-feeding**

Stop breast-feeding while taking Prefibin as it will pass into your milk and may harm the breast-fed child

**Driving and using machines**

Do not drive or use machines if you feel drowsy or dizzy while being treated with this medicine. Prefibin can impair alertness and the ability to react. Therefore, ask your doctor whether and under what circumstances you can drive a vehicle, for example.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine

**Prefibin contains lactose and sodium**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. This medicine contains less than 1 mmol sodium (23 mg) per sublingual tablet, that is to say essentially 'sodium-free'.

### 3 How to take Prefibin

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

**The recommended dose is:**

- Take the dose once a day unless otherwise prescribed by your doctor.

Your doctor will determine the best dose for you. During your treatment, the doctor may adjust the dose, depending upon your response.

If your craving for drugs is not suppressed completely, please inform your doctor. The suitable dose is found, if you do not experience symptoms of withdrawal. However, too high doses will result in sedation or drowsiness.

**Patients with reduced liver function**

Your doctor will probably prescribe a lower dose. However, you must not use Prefibin if you have serious liver diseases.

**Method of use**

The tablets are described as "sublingual". This means that the tablet should be **placed under the tongue** and kept there until fully dissolved. This usually takes 5 to 10 minutes. This form of use is the only effective administration route for this medicine.

Do not suck, chew or swallow the tablets whole – the medicine will not work this way. Do not swallow or consume food or drink until the tablet is completely dissolved.

*Prefibin 2mg and 8mg sublingual tablets*

The sublingual tablets can be divided into equal doses.

Only sublingual application is allowed. Other forms of application (such as intravenous misuse) may lead to life-threatening intoxications with buprenorphine. In addition, excipients of the tablet and bacterial contamination may lead to health hazards such as hypersensitivity reactions, shock, inflammation of the heart, thromboembolism and sepsis.

**Duration of use**

This will be decided by your doctor.

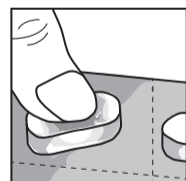
After a period of successful treatment, the doctor may gradually reduce the dose to a lower maintenance dose. Depending on your condition, the Prefibin dose may be further reduced under careful medical supervision, eventually it may be stopped.

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

The effectiveness of this treatment depends:

- upon the dose.
  - combined with the associated medical, psychological and social treatment.
- If you have the impression that the effect of Prefibin is too strong or too weak, talk to your doctor or pharmacist.

**Instruction for use**



Remove the sublingual tablets from the blister by pressing down on the whole tablet, so you need the least effort and you prevent the tablets from being crushed.

**If you take more Prefibin than you should**

Tell your doctor immediately or contact your nearest hospital casualty department. You might need urgent medical treatment. Bring the pack and any remaining tablets with you.

**If you forget to take Prefibin**

Tell your doctor as soon as possible and follow his/her instructions. Do not take a double dose to make up a forgotten tablet, unless your doctor tells you to do so.

**If you stop taking Prefibin**

Do not suddenly stop taking the tablets unless told by your doctor, as this may cause withdrawal symptoms. 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.

**Tell your doctor immediately or seek urgent medical attention** if you experience side effects such as:

- Sudden wheezing, difficulty breathing, swelling of the eye lids, face, tongue, lips, throat or hands; rash or itching especially those covering your whole body. These may be signs of a life threatening allergic reaction
- If you start to breathe more slowly or weakly than expected (respiratory depression)
- If you start to feel faint, as this may be a sign of low blood pressure

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

- Severe fatigue (tiredness), have no appetite or if your skin or eyes look yellow. These may be symptoms of liver damage.

Side effects can occur with the following frequencies:

**Very common**, may affect more than 1 in 10 people

- sleeplessness
- headache
- nausea (feeling sick)
- increased sweating
- withdrawal symptoms such as feeling sick, diarrhoea, anxiety or shivering
- pain

**Common**, may affect up to 1 in 10 people

- bronchitis
- infection including influenza
- sore throat and painful swallowing
- swelling and irritation inside the nose
- swollen glands (lymph nodes)
- decreased appetite
- agitation, anxiety
- depression, hostility, nervousness, paranoia, thinking abnormal
- sleepiness, dizziness, increased muscle tension
- migraine
- tingling or numbness in the hands or feet
- shaking
- flow of tears
- widening of the pupil (black part in the eye)
- fainting
- feeling your heartbeat
- flushing
- fall in blood pressure when standing up quickly
- cough, difficulty breathing, yawning
- abdominal pain, constipation, diarrhoea, dry mouth, indigestion, wind (flatulence), vomiting, stomach problems
- tooth disorder
- skin rash
- joint, back and bone pain
- muscle spasms and pain
- neck pain
- painful periods
- weakness
- chest pain
- chills, generally feeling unwell
- swelling (hands and feet)
- fever

**Uncommon**, may affect up to 1 in 100 people

- seeing, feeling or hearing things that are not there (hallucinations)
- short and shallow breathing
- liver cell destruction and inflammation

**Frequency not known**, frequency cannot be estimated from the available data

- cramps of bronchial muscles
- life-threatening allergic shock reaction
- serious allergic reaction which causes swelling of the face or throat
- a feeling of dizziness or spinning
- drug dependence
- difficulty passing urine
- Withdrawal effects in newborn infants after their mothers have used Prefibin

Misusing this medicine by injecting it can cause withdrawal symptoms, infections, other skin reactions and potentially serious liver problems.

**Reporting of side effects**

If you get 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 via the Yellow Card Scheme: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in Google play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

### 5 How to store Prefibin

**Keep this medicine out of the sight and reach of children.**

Do not use this medicine after the expiry date, which is stated on the carton and plastic/aluminium strip after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

### 6 Contents of the pack and other information

**What Prefibin contains:**

The **active substance** is **buprenorphine** as buprenorphine hydrochloride.

*Prefibin, 2 mg, sublingual tablets*

Each tablet contains 2 mg buprenorphine.

*Prefibin, 8 mg, sublingual tablets*

Each tablet contains 8 mg buprenorphine.

- The other ingredients are citric acid anhydrous, lactose monohydrate, mannitol, sodium citrate, sodium stearyl fumarate, pregelatinised starch (maize).

**What Prefibin looks like and contents of the pack**

*Prefibin, 2 mg, sublingual tablets*

Prefibin 2 mg sublingual tablets are white to off-white, oval tablets with a breaking notch on both sides (9.4 x 4.0 mm).

*Prefibin, 8 mg, sublingual tablets*

Prefibin 8 mg sublingual tablets are white to off-white, oval tablets with a breaking notch on both sides (13.5 x 6.6 mm).

Your medicine is available in plastic/aluminium strips containing 7, 10, 20, 24, 28, 30, 48 or 50 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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RG12 1RF

**Manufacturer**

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