

# Prefibin 0.4 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 the 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 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

**This medicine contains buprenorphine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.**

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

Prefibin is used to treat dependence on opiate (narcotic) drugs, such as morphine and heroin in drug addicts who have agreed to be treated for their addiction.

Prefibin is used in adults and adolescents over 16 years of age who are also receiving medical, social and psychological support.

This medicine contains buprenorphine which belongs to a class of medicines called opioids. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction, and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

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

### Do not take Prefibin

- If you are a child under the age of 16 years
- If you are allergic to buprenorphine or any of the other ingredients of this medicine (listed in section 6)
- If you have **serious breathing problems**
- If you have **serious problems with your liver**
- If you are intoxicated due to alcohol or have trembling, sweating, anxiety, confusion or hallucinations caused by alcohol
- If you are breast feeding a baby

### Warnings and precautions

#### Tolerance, dependence, and addiction

This medicine contains buprenorphine which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance).

Repeated use of Prefibin can also lead to dependence, abuse, and addiction, which may result in life-threatening overdoses.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Prefibin if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Prefibin, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Prefibin).

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

- seizures, fits or convulsions
- asthma or other breathing problems
- You must not use Prefibin if you have serious breathing problems.
- recently suffered head injury or brain disease
- reduced kidney function or any kidney disease
- reduced liver function or any liver disease such as hepatitis

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.

- low blood pressure
- a urinary disorder (especially linked to enlarged prostate in men)
- thyroid problems
- adrenocortical disorder (e.g. Addison's disease)
- bile problems
- you are below 18 years or over 65 years old
- 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").

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.

### Important things to be aware of :

#### Misuse, abuse and diversion

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. Opioids should only be used by those they are prescribed for.

**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. Taking higher doses or more frequent doses of opioid may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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

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

**Breathing problems**  
Some people have died from respiratory failure (inability to breathe) because they misused this medicine or took it in combination with other central nervous system depressants, such as alcohol, benzodiazepines (tranquilisers), or other opioids.

#### Addiction and withdrawal symptoms

Taking this medicine regularly, particularly for a long time, can lead to addiction.

Addiction can cause withdrawal symptoms when you stop taking this medicine.

Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

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.

#### Liver damage

Liver damage has been reported after taking Prefibin, especially when the medicine is misused. This could also be due to viral infections (chronic hepatitis C), alcohol abuse, anorexia or use of other medicines with the ability to harm your liver (see section 4).

**Regular blood tests may be conducted by your doctor to monitor the condition of your liver. Tell your doctor if you have any liver problems before you start treatment with Prefibin.**

#### Blood pressure

This product may cause your blood pressure to drop suddenly, causing you to feel dizzy 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 some diseases. Do not forget to advise your doctor if you take 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.

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 16 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.

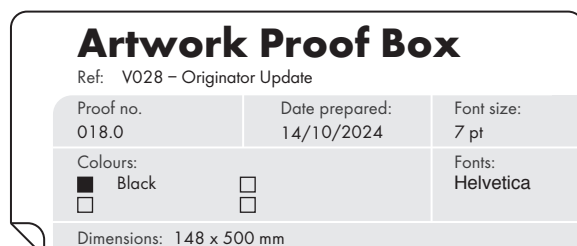
Some medicines may increase the side effects of Prefibin and may sometimes cause very serious reactions. Do not take any other medicines whilst taking Prefibin without first talking to your doctor, especially:

The following medicines can affect or be affected by Prefibin:

- Benzodiazepines (used to treat anxiety or sleep disorders) such as diazepam, temazepam, alprazolam. 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.
- **Gabapentin or Pregabalin** to treat epilepsy or pain due to nerve problems (neuropathic pain)
- **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 **medicines that may make you feel sleepy** which are used to treat illnesses such as anxiety, sleeplessness, convulsions / seizures, pain. These types of medicines will reduce your alertness levels making it difficult for you to drive and use 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.
  - antidepressants (used to treat depression) such as isocarboxazide, phenelzine, selegeline, tranylcypromine, and valproate may increase the effects of this medicine.
  - sedative H1 receptor antagonists (used to treat allergic reactions) such as diphenhydramine and chlorphenamine.
  - barbiturates (used to cause sleep or sedation) such as phenobarbital, secobarbital.
  - tranquilisers (used to cause sleep or sedation) such as chloral hydrate.
- 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. Naltrexone may prevent Prefibin from working. If you take naltrexone whilst you are taking Prefibin you may experience a sudden onset of prolonged and intense withdrawal symptoms.
- **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
- **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.
- **valproate** (used to treat epilepsy, bipolar disorder and to prevent migraine headaches)
- **medicines to treat allergies**, sleep disturbances or cold; or prevent and treat nausea and vomiting; such as doxylamine, diphenhydramine
- **medicines used to treat allergies, travel sickness or nausea** (antihistamines or antiemetics)
- **medicines to treat mental or anxiety disorders**, with sedative effects, such as chlorpromazine, haloperidol
- **medicines to treat psychiatric disorders** (antipsychotics or neuroleptics)
- **muscle relaxants**
- certain medicines to treat high blood pressure, such as **clonidine**

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- Anti-retrovirals (used to treat AIDS) such as ritonavir, nelfinavir, indinavir may increase the effects of this medicine
- Some antifungal agents (used to treat fungal infections) such as ketoconazole and itraconazole and certain antibiotics (macrolides) used to treat bacterial infections may extend the effects of this medicine
- Some medicines may decrease the effect of Prefibin. These include medicines used to treat epilepsy (such as phenobarbital, carbamazepine, phenytoin) and medicines used to treat tuberculosis (rifampicin).

To get the greatest benefit from taking Prefibin, you must tell 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 for you by your doctor.

**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. 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.

Do not take Prefibin if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby. If you use Prefibin during pregnancy, your baby may become dependent and experience withdrawal symptoms including problems with breathing after the birth which may need to be treated. These symptoms may occur several days after birth.

Do not take Prefibin while you are breastfeeding as buprenorphine passes into breast milk and will affect your baby.

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

**Prefibin contains sodium**  
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.

To avoid sudden withdrawal symptoms, treatment with Prefibin should be given when there are already clear signs of withdrawal symptoms.

Your prescriber should discuss your treatment and whether you need to continue taking tablets at regular intervals. If you and your prescriber decide to stop treatment, a plan will be put in place to gradually reduce the dose and stop taking the medicine to minimise the risk of withdrawal effects.

**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.

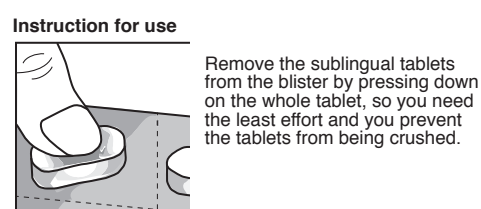
The score line is not intended for breaking the sublingual tablets.

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.



**If you take more Prefibin than you should**  
If you or someone else takes too much of this medicine, you must go or be taken immediately to an emergency centre or hospital as overdose with Prefibin may cause serious and life-threatening breathing problems.

**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 for the forgotten dose.

**If you stop taking Prefibin**  
Do not change the treatment in any way or stop treatment without the agreement of the doctor who is treating you. Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty

sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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 eyelids, 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
- runny or stuffy 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
- tearing (watery eyes) disorder
- dilation 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
- shortness of breath
- abdominal pain, constipation, diarrhoea, dry mouth, indigestion, wind (flatulence), gastrointestinal disorder, 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
- malaise
- palpitations
- somnolence
- tremor
- vomiting (being sick)

**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 and addiction
- difficulty passing urine
- withdrawal effects in newborn infants after their mothers have used Prefibin
- dental caries
- seizures
- drop in blood pressure on changing position from sitting or lying down to standing
- vertigo

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

**Drug Withdrawal**  
When you stop taking Prefibin, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**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 the 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

**Store this medicine in a safe and secure place, where other people cannot access it. It can cause serious harm and be fatal to people who may take this medicine by accident, or intentionally when it has not been prescribed for them. 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. Each sublingual tablet contains 0.4 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 0.4 mg sublingual tablets are white to off-white, round, biplane tablets with facet and one-sided ornamental notch (diameter: approximately 5.0 mm). Your medicine is available in plastic/aluminium strips containing 7, 10, 20, 24, 28, 30, 48 or 50 sublingual tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder**  
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Watchmoor Park, Camberley, Surrey  
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**Manufacturer**  
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