

PACKAGE LEAFLET: INFORMATION FOR THE USER

Buprenorphine 2 mg and 8 mg Sublingual Tablets

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

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. See section 4.

What is in this leaflet:

1. What Buprenorphine Sublingual Tablets are and what they are used for
2. What you need to know before you take Buprenorphine Sublingual Tablets
3. How to take Buprenorphine Sublingual Tablets
4. Possible side effects
5. How to store Buprenorphine Sublingual Tablets
6. Contents of the pack and other information

1. What Buprenorphine Sublingual Tablets are and what they are used for

This medicine has been prescribed for you for substitution (replacement) treatment in patients who are addicted to opioid drugs such as heroin and morphine.

It contains the buprenorphine which belongs to a class of medicines called opioids, which are 'pain relievers'.

This medicine has been prescribed/provided 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.

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

2. What you need to know before you take Buprenorphine Sublingual Tablets

Do not take Buprenorphine Sublingual Tablets if you:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Buprenorphine Sublingual Tablets if you:

- have asthma or breathing problems.
- have any kidney problems.
- have any liver disease such as hepatitis
- have low blood pressure.
- have recently suffered head injury or brain disease.
- have a urinary disorder (especially linked to enlarged prostate in men).
- have any kidney disease

- have thyroid problems.
- have adrenocortical disorder (e.g. Addison's disease).
- have depression or other conditions that are treated with antidepressants. The use of these medicines together with Buprenorphine Sublingual Tablets can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Buprenorphine Sublingual Tablets).
- suffer from seizures, fits or convulsions
- if you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- if you feel you need to take more of Buprenorphine Sublingual Tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever

Sleep-related breathing disorders

Buprenorphine Sublingual Tablets 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.

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

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

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.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. 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.

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. **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 this medicine or took it in combination with other central nervous system depressants, such as alcohol, benzodiazepines (tranquilisers), or other opioids.

- **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 Buprenorphine Sublingual Tablets can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose.

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 Buprenorphine Sublingual Tablets 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 Buprenorphine Sublingual Tablets, 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 Buprenorphine Sublingual Tablets).

- **Withdrawal symptoms**

This product can cause withdrawal symptoms if you take it less than 6 hours after you use a short-acting opioid (e.g. morphine, heroin) or less than 24 hours after you use a long-acting opioid such as methadone.

Buprenorphine Sublingual Tablets can also cause withdrawal symptoms if you stop taking it abruptly

- **Liver damage**

Liver damage has been reported after taking Buprenorphine Sublingual Tablets, 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 Buprenorphine Sublingual Tablets.**

- **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.

Other medicines and Buprenorphine Sublingual Tablets

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 Buprenorphine Sublingual Tablets and may sometimes cause very serious reactions. Do not take any other medicines whilst taking Buprenorphine Sublingual Tablets without first talking to your doctor, especially:

- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).
- medicines to treat depression: anti-depressants such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with buprenorphine 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.

The following medicines have sedative effects (make you feel sleepy/drowsy). These effects are increased if these medicines are taken while you are being treated with buprenorphine:

- Benzodiazepines (used to treat anxiety or sleep disorders) such as diazepam, temazepam, alprazolam. Your doctor will prescribe the correct dose for you. **Taking the wrong dose of benzodiazepines may cause death due to respiratory failure (inability to breathe).**
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics);
- medicines to treat psychiatric disorders (antipsychotics or neuroleptics);
- muscle relaxants;
- medicines to treat Parkinson's disease;
- **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, selegiline, 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.
- Naltrexone may prevent Buprenorphine from working. If you take naltrexone whilst you are taking buprenorphine you may experience a sudden onset of prolonged and intense withdrawal symptoms.
- Clonidine (used to treat high blood pressure) may extend the effects of this medicine.
- 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 (macrolide) may extend the effects of this medicine.
- Some medicines may decrease the effect of buprenorphine. These include medicines used to treat epilepsy (such as carbamazepine and phenytoin) and medicines used to treat tuberculosis (rifampicin).

To get the greatest benefit from taking buprenorphine, 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.

Buprenorphine Sublingual Tablets with food and drink

Alcohol may increase drowsiness and may increase the risk of respiratory failure (inability to breathe) if taken with Buprenorphine Sublingual Tablets. **Do not take Buprenorphine Sublingual Tablets together with alcohol.** Do not swallow or consume food or drink until the tablet is completely dissolved.

Pregnancy and breast-feeding

Do not take Buprenorphine Sublingual Tablets 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 Buprenorphine Sublingual Tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

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

Driving and using machines

If you feel drowsy or dizzy while taking these tablets do not use machinery.

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:
 - o The medicine has been prescribed to treat a medical or dental problem and
 - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - o 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.

Buprenorphine Sublingual Tablets contain lactose

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

Important information about Buprenorphine Sublingual Tablets

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

3. How to take Buprenorphine Sublingual Tablets

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

Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

You must place the tablet under your tongue (sublingual) and allow it to dissolve, which will take 5 to 10 minutes. This is the only way to take the tablets. Do not chew or swallow them whole, as they will not work

Your doctor will tell you how many tablets to take and you should always follow this advice.

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

Adults and children over the age 16 years: when beginning treatment the dose is between 0.8 mg to 4 mg, taken once a day.

For drug addicts who have not had any withdrawal treatment: one dose of buprenorphine should be taken at least 6 hours after the last use of the opioid (narcotic such as morphine or heroin), or when the first signs of craving appear. If you take it less than six hours after you use a narcotic you may get withdrawal symptoms.

For patient taking methadone: before beginning treatment, your doctor should reduce your dose of methadone to not more than 30 mg a day. Buprenorphine Sublingual Tablets may cause withdrawal symptoms in patients who are dependent on methadone, if used within 24 hours of the last dose methadone.

During your treatment, your doctor may increase your dose of Buprenorphine Sublingual Tablets to a maximum single daily dose of 32 mg, depending upon your response. Once you have been stable for a while, your doctor will gradually reduce your dose and it may be possible to stop it altogether. Do not suddenly stop taking the tablets, as this may cause withdrawal symptoms.

If you take more Buprenorphine Sublingual Tablets 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 Buprenorphine Sublingual Tablets may cause serious and life-threatening breathing problems.

If you forget to take Buprenorphine Sublingual Tablets

Tell your doctor as soon as possible if you miss a dose and follow his or her instructions. Do not take a double dose to make up for the forgotten dose.

If you stop taking Buprenorphine Sublingual Tablets

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 everyone gets them.

Tell your doctor immediately or seek urgent medical attention

If you experience side effects such as:

- sudden wheeziness, difficulty breathing, swelling of the eyelids, face, lips, throat or hands; rash or itching especially those covering your whole body. These may be signs of life threatening allergic reaction.
- if you start to breath 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), loss of appetite or if your skin or eyes look yellow. These may be symptoms of liver damage.

The frequency of possible side effects listed below is defined using the following convention:

- very common (may affect more than 1 in 10 people)

- common (may affect up to 1 in 10 people)
- not known (frequency cannot be estimated from the available data).

Side effects reported with Buprenorphine Sublingual Tablets
<i>Very common side effects:</i>
Drug withdrawal syndrome, headache, hyperhidrosis (sweating), insomnia (inability to sleep), nausea (feeling sick), pain
<i>Common side effects:</i>
Abdominal pain, agitation, anxiety, joint pain, weakness, back pain, bone pain, bronchitis, chest pain, chills, constipation, cough, decreased appetite, depression, diarrhoea, dizziness, dry mouth, painful period, indigestion, shortness of breath, flatulence, gastrointestinal disorder, hostility, increase in muscle tension, infection, influenza, nervousness, tearing (watery eyes) disorder, swollen glands (lymph nodes), malaise, migraine, muscle spasms, muscle pain, dilation of the pupil, neck pain, palpitations, paranoia, burning or tingling in hands and feet, swelling (hands and feet), sore throat and painful swallowing, fever, rash, somnolence, syncope (fainting), thinking abnormal, tooth disorder, tremor; flushing, vomiting (being sick), yawning
<i>Frequency not known:</i>
Drug Dependence and addiction (see section ‘How do I know if I am addicted’), seizures, drug withdrawal syndrome in new born, hallucinations (sensing things that are not real), drop in blood pressure on changing position from sitting or lying down to standing, difficulty in urinating.
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 Buprenorphine Sublingual Tablets, 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.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Buprenorphine Sublingual Tablets, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Buprenorphine Sublingual Tablets

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

Store your medicine in the original packaging to protect from moisture.

Do not store above 30°C.

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

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

6. Contents of the pack and other information

What Buprenorphine Sublingual Tablets contain

- The active substance is buprenorphine (as buprenorphine hydrochloride). Each tablet contains 2 mg or 8 mg of buprenorphine.
- The other ingredients are lactose monohydrate, mannitol (E421), maize starch, citric acid (anhydrous), sodium citrate, povidone (plasdone K29/32), magnesium stearate, ascorbic acid and edetic acid (EDTA).

What Buprenorphine Sublingual Tablets look like and the contents of the pack

Buprenorphine 2 mg Sublingual Tablets are off-white to brownish, oval, biplane tablets marked with “B2” on one side.

Buprenorphine 8 mg Sublingual Tablets are off-white to brownish, oval, biplane tablets marked with “B8” on one side.

Your medicine is available in blisters containing 7, 14, or 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aspire Pharma (Malta) Limited
Trident Park, Notabile Gardens
No. 2, Level 3, Mdina Road
Central Business District
Birkirkara CBD2010
Malta

Manufacturer

SMB TECHNOLOGY S.A.
39 rue du Parc Industriel
6900 Marche en Famenne, Belgium

This leaflet was last revised in September 2024.