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Package leaflet: Information for the patient

Buprenorphine 0.4mg, 2mg and 8mg 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.
- The full name of this medicine is Buprenorphine 0.4mg, 2mg and 8mg Sublingual Tablets but within the leaflet it will be referred to as Buprenorphine tablets.

What is in this leaflet:

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

1 What Buprenorphine tablets are and what they are used for

This medicine has been prescribed for you for use as part of a medical, social and psychological treatment programme for patients addicted to opiate (narcotic) drugs.
It 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 doctor should have explained how long you will be taking it for, when it is appropriate to stop and how to do this safely.

A sublingual tablet is a tablet that is placed under your tongue and allowed to dissolve.
Treatment is prescribed and monitored by physicians who are specialists in the treatment of drug dependence.
Treatment with Buprenorphine tablets is intended for use in adults and adolescents over 16 years of age.

2 What you need to know before you take Buprenorphine tablets

Do not take Buprenorphine tablets if you:
- are **allergic** to buprenorphine or any of the other ingredients of this medicine (listed in section 6)
- are a child under **16 years of age**
- have **serious breathing** problems
- have serious problems with your **liver**
- are **intoxicated** due to alcohol or have **delirium** tremens (the "shakes" and hallucinations)
- are **breast-feeding**
- are taking **naltrexone** or **nalmefene** for the treatment of **alcohol** or **opioid dependence**.

Warnings and precautions
Tell your doctor if you have any of the following illnesses before treatment or develop them during treatment, as your doctor may need to reduce your dose of Buprenorphine tablets or you may need extra treatment to control them:
- **asthma** or other breathing problems
- **liver** or **kidney** problems. If you suffer from **serious liver insufficiency** you must not take buprenorphine
- **head injuries** or **brain disease**
- **low blood pressure**
- **enlarged prostate gland**, which can make it difficult to pass water
- **difficulties passing water** because of narrowing of the urethra (urethral stenosis)
- **thyroid problems** or **adrenocortical disorder** (e.g. Addison's disease)
- **depression** or other conditions that are treated with **antidepressants**. The use of these medicines together with Buprenorphine can lead to serotonin syndrome, a potentially life-threatening condition (see 'Other medicines and Buprenorphine tablets')
- if you suffer from **seizures, fits or convulsions**.

Sleep-related breathing disorders
Buprenorphine 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.

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 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 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 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 tablets').

Misuse, abuse and diversion
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 doctor 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 six hours after you use a narcotic (morphine, heroin or other related products) or less than 24 hours after you use methadone.

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 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.

Misuse, especially by injection and at high dose is dangerous and could be fatal.
Serious cases of infections with potential fatal outcome may occur in a context of misuse of Buprenorphine tablets, when administered by the intravenous route.

Some people have died from respiratory failure (inability to breathe) because they misused buprenorphine or took it in combination with other central nervous system depressants such as alcohol, benzodiazepines (medicines used to treat anxiety or sleep disorders) or other opioids.

Cases of acute hepatic injury (liver problems) have been reported in a context of misuse, especially by intravenous route and at a high dose. These injuries could be due to special conditions such as viral infections (chronic hepatitis C), alcohol abuse, anorexia, or when taken with certain other medicines (for example: antiretroviral nucleoside analogues, acetylsalicylic acid (aspirin), amiodarone, isoniazid and valproate). If you have symptoms of severe tiredness, no appetite, itching or if your skin or eyes look yellow, tell your doctor immediately, so that you can receive the proper treatment.

This medicine can cause a sudden drop in blood pressure, causing you to feel dizzy if you get up too quickly from sitting or lying down.

Buprenorphine tablets may mask pain reflecting some diseases. Do not forget to inform your physician if you take this medicine.

The risk of serious side effects is greater if you use opioids, alcohol, sedatives and hypnotics, especially benzodiazepines.

Children and adolescents
Buprenorphine tablets should not be used in children and adolescents below the age of 16 years due to lack of data on safety and efficacy.

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

Before taking Buprenorphine tablets, you must tell your doctor if you are taking any of the following medicines:
- naltrexone and nalmefene (for the treatment of addictive disorders) may stop Buprenorphine from working. They must not be used with Buprenorphine to avoid a sudden onset of long-lasting and severe withdrawal symptoms
- other medicines with sedative properties including sedating antihistamines, certain antidepressants and clonidine (a treatment for high blood pressure, migraine, menopausal flushing)
- strong pain killers (opioid analgesics) and cough medicines containing opioid-related substances such as methadone and codeine
- barbiturates and other medicines used for the treatment of sleep disorders, anxiety or relievement of convulsions
- monoamine oxidase inhibitors (a type of antidepressant)
- antidepressants such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepin, 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
- medicines to treat psychiatric disorders (antipsychotics or neuroleptics)
- medicines to treat HIV / AIDS (protease inhibitors) including indinavir, ritonavir, nelfinavir and saquinavir
- anti-epileptic (anticonvulsant) medicines including phenobarbital, carbamazepine and phenytoin
- antibiotic medicines including rifampicin and erythromycin
- antifungal medicines including ketoconazole and itraconazole
- gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics)
- muscle relaxants
- medicines to treat Parkinson's disease
- Concomitant use of Buprenorphine tablets and sedative medicines such as benzodiazepines or related 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 Buprenorphine tablets together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell

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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.

Buprenorphine tablets with alcohol
Do not drink alcohol when you are being treated with buprenorphine. Alcohol increases the sedative effects of buprenorphine, which can make driving and operating machinery dangerous.

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
Do not take Buprenorphine tablets if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you take Buprenorphine tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breast-feeding
Do not take Buprenorphine tablets while you are breast-feeding as buprenorphine passes into breast milk and will affect your baby.

Driving and using machines
Buprenorphine may cause drowsiness. If you feel tired, do not drive or operate machinery.

This 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.

Buprenorphine tablets contain lactose and sunset yellow
Buprenorphine tablets contain lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Buprenorphine 2mg and Buprenorphine 8mg sublingual tablets also contain the colouring agent sunset yellow (E110), which may cause allergic reactions.

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

3 How to take Buprenorphine tablets

Your doctor should discuss your treatment and whether you need to continue taking tablets at regular intervals. If you and your doctor 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.

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

The tablets are administered sublingually. This means that you must place the tablet under your tongue and allow it to dissolve. This is the only way the tablets should be taken. Do not chew or crush the tablets or swallow them whole, as they will not work properly and you may get withdrawal symptoms.

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. To get the greatest benefit from taking Buprenorphine tablets, you must tell your doctor about all the medicines you are taking, including alcohol, medicines containing alcohol, street drugs, and any prescription medicines you are taking that have not been prescribed to you by your doctor.

After the first dose of Buprenorphine tablets, it is possible that you may have some opiate withdrawal symptoms, see section 4 'Possible side effects'.

Reduced kidney or liver function
If you have problems with your kidneys or liver, your dose may have to be reduced. Talk to your doctor. If you suffer from serious liver insufficiency, you must not take Buprenorphine tablets.

Treatment duration
The length of treatment will be determined individually by your doctor. Do not change the treatment in any way or stop treatment without the agreement of the doctor who is treating you.

The effectiveness of this treatment depends on the dose, in combination with the associated medical, psychological and social treatment.

If you have the impression that the effect of Buprenorphine tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more Buprenorphine tablets than you should
In case of overdose of Buprenorphine tablets, you must go or be taken immediately to an emergency centre or hospital for treatment. Immediately advise your doctor or your pharmacist. Symptoms of an overdose can include breathing difficulties, slow breathing or heart symptoms. Toxic poisoning has been observed after misuse (overdose or wrong administration) and in the worst case it can result in stopping breathing, heart failure and/or liver damage.

If you forget to take Buprenorphine tablets
Contact your doctor if you forget to take Buprenorphine tablets. Do not take a double dose to make up for a forgotten dose unless your doctor instructs you to do so.

If you stop taking Buprenorphine tablets
Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your doctor 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.

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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 help if you experience any of the following serious side effects:
- **allergic reactions** including difficulty in breathing, wheezing and swelling of eyes, lips, throat, tongue or hands; skin rash, hives and itching (very rare, may affect up to 1 in 10,000 people)
- severe difficulty in breathing (**respiratory depression**) (common, may affect up to 1 in 100 people)
- **bronchitis** (infection of the airways) (common, may affect up to 1 in 10 people)
- **arrhythmias** (common, may affect up to 1 in 10 people)
- severe fatigue, loss of appetite or yellowing of skin and eyes. These may be symptoms of **liver damage** such as hepatitis or death of the cells of the liver (necrosis of the liver) (not known, frequency cannot be estimated from the available data)
- **seizures** (not known, frequency cannot be estimated from the available data).

Misusing this medicine by injecting it can cause withdrawal symptoms, infections, other skin reactions and potentially serious liver problems - see section 2 'Warnings and precautions'.

After the first dose of Buprenorphine tablets, you may have some opiate withdrawal symptoms; signs are described in 'Drug Withdrawal' at the end of this section.

Other side effects:
Very common (may affect more than 1 in 10 people):
- not being able to sleep
- headache
- nausea
- excessive sweating
- pain.

Common (may affect up to 1 in 10 people):
- infections, the 'flu', sore throat, runny nose
- swollen or enlarged glands (lymph nodes)
- decreased appetite
- agitation, anxiety, depression, hostility, nervousness, paranoia, abnormal thoughts
- hallucination
- dizziness, increased muscle tone, migraine, 'pins and needles', drowsiness, fainting, tremor
- disorders of the tear ducts, vision impairment (dilated or constricted pupils)
- feeling of dizziness or spinning
- faster or irregular heartbeat (palpitations)
- widening of blood vessels, drop in blood pressure on changing position from sitting or lying down to standing
- cough, shortness of breath, yawning
- abdominal pain, constipation, diarrhoea, dry mouth, indigestion, stomach complaints, passing wind, tooth disorder, vomiting
- rash
- joint pain, back pain, bone pain, muscle spasms, muscle pain, neck pain
- painful periods in women
- physical weakness/ fatigue, chest pain, chills, a general feeling of discomfort, illness or unease, swelling in the lower legs or hands, fever.

Uncommon (may affect up to 1 in 100 people):
- double vision, pink eye (conjunctivitis)
- difficulty passing urine, pain or cramps in the lower abdomen (urinary disorders)
- drug withdrawal syndrome
- neonatal drug withdrawal syndrome.

Not known (frequency cannot be estimated from the available data):
- dependence and addiction
- dental caries.

Drug Withdrawal
When you stop taking Buprenorphine 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.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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 Buprenorphine Tablets

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, blister and label after EXP. The expiry date refers to the last day of that month.
Blister packs: Do not store above 25°C. Store in the original package in order to protect from moisture.
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.
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 protect the environment.

6 Contents of the pack and other information

What Buprenorphine tablets contain
- The active substance is buprenorphine (as buprenorphine hydrochloride). Each tablet contains 0.4mg, 2mg or 8mg of buprenorphine.
- The other ingredients are magnesium stearate, sodium citrate, povidone, citric acid, pregelatinised starch (maize), and lactose monohydrate. Buprenorphine 2mg and Buprenorphine 8mg sublingual tablets also contain crospovidone, mannitol and sunset yellow (E110).

What Buprenorphine tablets look like and contents of the pack
Buprenorphine 0.4mg sublingual tablets are uncoated, white or almost white, 6 mm round and flat with "B" on one side.
Buprenorphine 2mg sublingual tablets are uncoated, light orange, 5x8 mm oval and biconvex with "B" on one side.
Buprenorphine 8mg sublingual tablets are uncoated, light orange, 7.35x13.35 mm oval and biconvex with "B" on one side.

Pack size 7 tablets.

Marketing Authorisation Holder and Manufacturer
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This leaflet was last revised in October 2026.

If you would like a leaflet with larger text, please contact 01271 385257.