

Package leaflet: Information for the patient

Buprenorphine G.L. Pharma 200 microgram sublingual tablets Buprenorphine G.L. Pharma 400 microgram sublingual tablets

buprenorphine

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
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1. What buprenorphine sublingual tablets are and what they are used for

This medicine has been prescribed for you and is a strong pain killer that helps lessen moderate or severe pain.

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

The full name of your medicine is ‘Buprenorphine G.L. Pharma 200 microgram sublingual tablets’ or ‘400 microgram sublingual tablets’. These are referred to as ‘buprenorphine sublingual tablets’ throughout this leaflet.

2. What you need to know before you take buprenorphine sublingual tablets

Do not take buprenorphine

- if you are allergic to buprenorphine, to any of the other ingredients of this medicine (listed in section 6) or to other opiates (drugs which are morphine – like in their action).

Warnings and precautions

Talk to your doctor or pharmacist before taking buprenorphine, if you:

- suffer from seizures, fits or convulsions.
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

- 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.
- have problems with your liver.
- have breathing problems or are taking medicines with may make your breathing slower or weaker.
- have 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').

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 can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

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 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, 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 might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.
- 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).

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.

Athletes must be aware that this medicine may cause a positive reaction to 'anti-doping' tests.

Other medicines and buprenorphine

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

Buprenorphine should not be taken with

- medicines containing gestodene (a hormone),
- antibiotic medicines (troleandomycin, rifampicin),
- medicines to treat fungal infections (ketoconazole),
- medicines for depression (norfluoxetine),
- medicines for HIV infection (protease inhibitors: ritonavir, indinavir, saquinavir),
- medicines for epilepsy or pain due to nerve problems/ neuropathic pain (gabapentin or pregabalin, carbamazepine, phenytoin, phenobarbital),
- other opioid medicines.

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

- Medicines used to treat depression known as monoamine oxidase inhibitors (examples include tranylcypromine, phenelzine).
- 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.
- 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.
- Medicines to help you sleep (for example tranquilisers, hypnotics or sedatives).
- Sedative medicines such as benzodiazepines or related drugs:
Concomitant use of buprenorphine 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 sublingual tablets 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.

You should visit your doctor regularly whilst you are taking these medicines at the same time as buprenorphine.

Buprenorphine sublingual tablets with alcohol

Do not drink alcohol while you are taking this medicine as it may make you feel drowsy.

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 this medicine 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 this medicine during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

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

Driving and using machines

If you feel drowsy while taking these tablets do not drive or use machines.

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:
 - 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.

The new driving offence concerning driving after drugs have been taken applies in Great Britain. There is further information for patients who are intending to drive in Great Britain available at: <https://www.gov.uk/drug-driving-law>

Buprenorphine sublingual tablets contain lactose

This medicine 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.

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

3. How to take buprenorphine sublingual tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. **Do not take more tablets than your doctor has told you to.**

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using buprenorphine sublingual tablets, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, If you stop taking Buprenorphine sublingual tablets).

Adults and children over 12 years of age

The usual dose is one or two 200 microgram tablets every six to eight hours or one 400 microgram tablet every six to eight hours, or as required. Place the tablet under your tongue and let it dissolve. Do not swallow or chew the tablet.

Children between 6 years and 12 years of age

The dose depends on their weight and your doctor will tell you the correct dose for your child.

This product should not be given to infants and children under 6 years of age.

If you take more buprenorphine sublingual tablets than you should

If you accidentally take too many tablets, you must get medical help at once. Take any remaining medication, the carton and the leaflet with you when seeking medical attention.

If you forget to take buprenorphine sublingual tablets

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a missed 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 everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are rare, these symptoms can be serious

- if you get any sudden wheeziness, difficulty breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body. These may be signs of an 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.

Other side effects that may occur with buprenorphine are:

- **Effects on your stomach or intestine:** feeling sick, being sick, dental caries (frequency not known (frequency cannot be estimated from the available data)).
- **Effects on your nervous system:** dizziness, hallucinations (sensing things that are not real), drowsiness, headaches, sweating.
- **Effects on your bladder:** difficulty in urinating.
- **Effects on your eyes:** blurred vision
- **Dependence and addiction:** frequency not known (cannot be estimated from the available data, see section ‘How do I know if I am addicted?’)
- **Seizures:** frequency not known (cannot be estimated from the available data)
- **Drug withdrawal:** When you stop taking buprenorphine 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.

Side effects that may occur when buprenorphine is used as substitution treatment are fever, diarrhoea, loss of appetite, dark urine, yellowing of the eyes and skin, difficulty with balance and walking, tremor and impaired speech.

If any of the side effects get 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 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 sublingual tablets

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

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 use this medicine after the expiry date which is stated on the carton and blister 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 protect the environment.

6. Contents of the pack and other information

What buprenorphine sublingual tablets contain

The active substance is buprenorphine.

Buprenorphine G.L. Pharma 200 microgram sublingual tablets

Each sublingual tablet contains 200 micrograms of buprenorphine (equivalent to 216 micrograms buprenorphine hydrochloride).

Buprenorphine G.L. Pharma 400 microgram sublingual tablets

Each sublingual tablet contains 400 micrograms of buprenorphine (equivalent to 432 micrograms buprenorphine hydrochloride).

The other ingredients are:

Lactose monohydrate, mannitol, maize starch, povidone K30, citric acid monohydrate, sodium citrate, magnesium stearate.

What buprenorphine sublingual tablets look like and contents of the pack

Buprenorphine G.L. Pharma 200 microgram sublingual tablets are white to off-white, round, biconvex tablets, debossed with 'I' on one side, with a diameter of approximately 5 mm.

Buprenorphine G.L. Pharma 400 microgram sublingual tablets are white to off-white, round,

biconvex tablets, with a diameter of approximately 5 mm.

The sublingual tablets are packed in blisters consisting of aluminium (base foil) laminated with aluminium sheets with 7, 50, 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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