Package leaflet: Information for the patient

Buprenorphine G. L. Pharma 0.2 mg, sublingual tablets
Buprenorphine G. L. Pharma 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 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 <INVENTED NAME> is and what it is used for

<INVENTED NAME> belongs to a class of medicines called opioids, which are 'pain relievers'.
<INVENTED NAME> is used to relieve severe pain after operations, in adults.

2. What you need to know before you take <INVENTED NAME>

Do not take <INVENTED NAME>
- if you are allergic to buprenorphine, centrally acting analgesics or any of the other ingredients of this medicine (listed in section 6),
- if you have severe respiratory insufficiency,
- if you have severe problems with your liver,
- if you have acute alcoholism or have delirium tremens
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Warnings and precautions
Talk to your doctor or pharmacist before taking <INVENTED NAME>
- if you have breathing problems (for example chronic obstructive pulmonary disease, asthma, cor pulmonale, decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression),
- if you have experienced head or brain injuries or have increased pressure in your head,
- if you have a history of drug abuse or emotional lability,
- if you are currently being treated or recently have been treated with medication that affects the central nervous system (such as making you sleepy) or slows your breathing,
- if have problems with your liver, if you have a biliary tract disease,
- if have problems with your kidneys or adrenal insufficiency (Addison's disease),
- if you have a depression or other conditions that are treated with antidepressants.
- The use of these medicines together with <INVENTED NAME> can lead to serotonin syndrome, a potentially life-threatening condition (see 'Other medicines and <INVENTED NAME>'),
- in case of acute abdominal pain,
- in case of myxoedema (swelling of the skin and soft tissue that occurs in patients with thyroid gland dysfunction) or hypofunction of the thyroid gland (hypothyroidism),
- in the case of drug-induced mood disorder (toxic psychosis), central nervous system depression,

or coma,
- if you have an enlarged prostate (prostatic hypertrophy) or ureteral stenosis (a blockage in the tubes (ureters) that carry urine from the kidneys to the bladder),
- if you have a spine curvature that affects your breathing,
- if you have recently been treated with narcotic pain relievers,
- if you are addicted to opioids, such as methadone or heroin, as you may experience withdrawal symptoms.

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 <INVENTED NAME> 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 <INVENTED NAME> 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 <INVENTED NAME>, 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 <INVENTED NAME>).

This medicine may be of interest to people who abuse prescription medicines and should therefore be kept theft-proof. **Do not give your medicine to anyone else.** Overuse and misuse can lead to overdose and/or death.

The use of this medicine can cause a sudden drop in blood pressure, which causes dizziness if you get up too quickly from sitting or lying down.

Sleep-related breathing disorders
<INVENTED NAME> can lead to sleep-related breathing issues, such as sleep apnoea (pauses in breathing during sleep) and sleep-related hypoxemia (low oxygen levels in the blood). These conditions may cause symptoms like breathing pauses during sleep, waking up frequently due to shortness of breath, difficulty sleeping through the night, or feeling excessively sleepy during the day. If you or someone else notices these symptoms, consult your doctor. Your doctor may consider reducing the dosage of the medication.

Children and adolescents
This medicine should not be used in children and adolescents since the effect and risks are unknown.

Elderly and debilitated patients
This medicine should be used with caution in elderly and debilitated patients.

Other medicines and <INVENTED NAME>
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 <INVENTED NAME> and may sometimes cause very serious reactions. Do not take other medicines whilst taking <INVENTED NAME> without first talking to your doctor, especially:

- Benzodiazepines, such as diazepam, temazepam, and alprazolam, which are used to treat anxiety or sleep disorders.
  Use of <INVENTED NAME> and sedative medicines such as benzodiazepines or related drugs at the same time increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening.
  Because of this, parallel use should only be considered when other treatment options are not possible. However, if your doctor does prescribe <INVENTED NAME> together with sedative medicines the dose and duration of simultaneous treatment should be limited by your doctor. Tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation. It might be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
  Taking the wrong dose of benzodiazepines can lead to death from respiratory failure.

  Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).
  - medicines to treat depression;
  - 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 drowsy.
  These medications are commonly used to treat conditions such as anxiety, insomnia, convulsions/seizures, and pain. When combined, they can reduce alertness, making it difficult to drive or operate machinery safely. Such combinations should be avoided, or if necessary, they should only be used under strict medical supervision. When such drug combinations are considered, it is important that the dose of one or both drugs be reduced.
  These medicines include:
  - other opioid pain relievers, such as methadone,
  - certain painkillers,
  - cough suppressants,
  - sedative medicines,
  - anaesthetics (halothane),
  - certain painkillers used for muscle relaxation,
  - certain antihypertensive medicines (clonidine and similar agents),
  - medicines used to treat depression, anxiety, or mental disorders,
  - certain medicines used to treat allergies (antihistamines).

- Antidepressants such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepin or trimipramine. These medicines may interact with <INVENTED NAME> and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control the movement of the eye, agitation, hallucinations, coma, excessive sweating, tremors, exaggerated reflexes, increased muscle tension and body temperature above 38 °C. Consult your doctor if you experience any of these symptoms.

- Antidepressants (MAO inhibitors). Avoid using <INVENTED NAME> if you have been treated with the antidepressants known as MAO inhibitors within the last 14 days. Combining these

medications can lead to potentially life-threatening interactions affecting vital functions such as the brain, breathing, and blood circulation. To ensure your safety, it is essential to wait for at least 2 weeks after discontinuing MAO inhibitors before starting treatment with <INVENTED NAME>. However, this interaction has been observed with opioids other than buprenorphine. You should not be treated with <INVENTED NAME> for 2 weeks after discontinuation of MAO inhibitors.

- Medicines that may increase or prolong the effect of this medicine:
  - antiretroviral medicines (used to treat AIDS, such as ritonavir, indinavir, saquinavir and atazanavir),
  - certain antifungal medicines (used to treat fungal infections such as ketoconazole),
  - certain antibiotics (used to treat bacterial infections such as erythromycin),
  - certain hormone treatments,
  - medicines that reduce blood flow to the liver**.**

- Medicines that may reduce the effect of this medicine:
  - medicines used to treat epilepsy,
  - medicines used to treat tuberculosis (for example, rifampicin).

- Taking <INVENTED NAME> along with naltrexone can block the pain-relieving effect of the medication and result in sudden long-lasting and severe withdrawal symptoms.

- <INVENTED NAME> may reduce the effectiveness of morphine and other pain relievers. If you are physically dependent on these substances, using <INVENTED NAME> could lead to withdrawal symptoms.

- Parallel use of <INVENTED NAME> along with phenprocoumon can lead to purpura - the development of red spots on the skin due to small bleeding underneath.

<INVENTED NAME> 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. Your doctor must decide whether you can use this medicine.

Pregnancy
There are no or limited data regarding the use of buprenorphine in pregnant women. Low-dose buprenorphine preparations must not be used during pregnancy unless absolutely necessary for the woman's clinical condition, in which case the pregnant woman, foetus, and newborn must be closely monitored by the physician.

During the later stages of pregnancy, taking high doses of buprenorphine can result in neonatal respiratory depression, even after short-term use.

Chronic use of buprenorphine during the last trimester of pregnancy may also lead to a neonatal withdrawal syndrome in the newborn.

Breast-feeding
Do not take this medicine while you are breast-feeding as buprenorphine passes into breast milk and can affect your baby.

Driving and using machines

When used as prescribed, buprenorphine has a minor to moderate influence on the ability to drive and use machines. This medicinal product can make you sleepy or dizzy or impair your thinking, especially upon initiation of therapy and dose adjustment. If you feel drowsy or dizzy while taking these tablets, do not drive or use machines.

This effect may be increased if buprenorphine is co-administered with alcohol or antidepressants ('Warnings and precautions' and 'Other medicines and <INVENTED NAME>' in section 2).

<INVENTED NAME> contains lactose and sodium

- This medicine contains lactose. If you are aware that you have an intolerance to some sugars, discuss this with 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 <INVENTED NAME>

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Before starting treatment and regularly during treatment the doctor will discuss with you:

- what you may expect from using this medicine
- when and how long you need to take it
- when to contact your doctor
- when you need to stop it (see also, If you stop taking <INVENTED NAME>).

The dose will be based on the severity of your pain and individual sensitivity. The doctor will tell you what dose you should take.

The effects of this medication generally occur within 30 minutes after you take the tablet and last approximately 6 to 8 hours. If you feel that the effect is either too strong or too weak, it is essential to talk to your doctor.

How to take the medicine

Place the tablet under your tongue and let it dissolve within 5 to 10 minutes. If you experience dry mouth, a few drops of liquid in the mouth can speed up the disintegration process. Do not suck, chew or swallow the tablet.

The sublingual tablets cannot be divided.

Doses

Standard dose for adults: A single dose of 0.2–0.4 mg, every 6-8 hours as needed.

For elderly patients, a single dose of 0.2 mg is sufficient in most cases.

Patients with liver problems

If you have liver problems, your doctor might prescribe a lower dose of this medicine. Please note that this medicine must not be used in patients with severe liver problems (see Do not take <INVENTED NAME>)

How long to take the medicine

The duration of treatment with <INVENTED NAME> depends on the type and severity of the pain and is determined by your doctor. It is crucial not to use this medication for a longer duration than necessary. If extended pain treatment is needed, it should be regularly evaluated and monitored at frequent intervals. In some cases, breaks in usage may be recommended to assess whether and at what dose <INVENTED NAME> should be used.

If you take more <INVENTED NAME> than you should

If you have taken more of this medicine than prescribed, you should immediately inform the nearest doctor you can reach. An overdose of this medication can lead to various severe symptoms, including:

- narrow pupils,

- troubles breathing, possibly progressing to respiratory arrest,
- impaired consciousness potentially leading to a coma,
- drop in blood pressure which can result in shock,
- bradycardia (slow heart rate),
- dizziness,
- nausea and vomiting

Overdose of strong opioids can have life-threatening consequences. Under no circumstances should you put yourself in situations that require increased attention, such as driving.

In the event of an overdose, until a doctor arrives, third parties can take the following measures:
- Keep the affected person awake and conscious, if possible,
- Give breathing commands to encourage regular breathing,
- Provide breathing assistance, if necessary, to maintain proper respiratory function.

If you forget to take <INVENTED NAME>
If you have used a lower dose of this medicine than intended or forgot to use it, you may experience inadequate or no pain relief. Continue using the tablets as prescribed by the doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking <INVENTED NAME>
If you want to interrupt or stop the treatment with <INVENTED NAME>, you should talk to your doctor about the reasons for the interruptions and the further course of treatment. With prolonged use of this medicine, physical dependence may develop. Sudden discontinuation of treatment will therefore be accompanied by withdrawal symptoms. These can include headaches, muscle aches, anxiety, tension, restlessness, confusion, irritability, recurrent insomnia, mood swings, hallucinations, and seizures.

To minimise the risk of experiencing withdrawal symptoms, it is important to gradually lower the dosage when discontinuing the treatment.

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.

Stop using <invented name> and immediately contact a doctor if you experience any of the following severe side effects:
- Anaphylactic shock (life-threatening hypersensitivity reaction with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness).
- Angioneurotic oedema (potentially fatal swelling of the face, neck, and throat)

These severe side effects have frequency very rare side effects and may affect up to 1 in 10,000 people.

Other side effects
Very common side effects (may affect more than 1 in 10 people):
- Sedation (feeling overly sleepy)
- Dizziness
- Vertigo (a sensation of spinning or dizziness)
- Nausea

Common side effects (may affect up to 1 in 10 people):
- Headache
- Constricted pupils (miosis)
- Low blood pressure when standing up (orthostatic hypotension)
- Hypoventilation (decreased breathing)
- Vomiting

- Increased sweating (hyperhidrosis)

Uncommon side effects (may affect up to 1 in 100 people):
- Confusion
- Euphoric mood
- Nervousness
- Depression
- Psychotic disorder (disturbance of perception)
- Hallucination
- Depersonalisation
- Speech disorder (dysarthria)
- Tingling or numbness sensation (Paraesthesia)
- Coma
- Tremor (trembling)
- Blurred vision
- Diplopia (double vision)
- Visual impairment
- Conjunctivitis (inflammation of the eye's outer lining)
- Tinnitus (ringing in the ears)
- Tachycardia (rapid heart rate)
- Bradycardia (slow heart rate)
- Cyanosis (bluish discoloration of the skin)
- Atrioventricular block second degree (a type of heart conduction problem)
- High blood pressure
- Pallor (pale skin)
- Dyspnoea (respiratory distress)
- Apnoea (respiratory arrest)
- Loss of appetite
- Constipation
- Dyspepsia (indigestion)
- Flatulence
- Pruritus (itching)
- Skin rash
- Urinary retention (difficulty emptying the bladder)
- Asthenia (weakness)
- Exhaustion
- Malaise (general feeling of discomfort or being unwell)

Rare side effects (may affect up to 1 in 1,000 people):
- Hypersensitivity reactions
- Decreased appetite
- Depressed mood
- Agitation
- Seizures
- Abnormal coordination
- Diarrhoea
- Urticaria

Very rare side effects (may affect up to 1 in 10,000 people):
- Bronchospasm (spasms of the bronchial muscles)

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

* The frequency of these adverse reaction reports is less than 1% of the reports during market observation.

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <INVENTED NAME>

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 blister after 'EXP'. The expiry date refers to the last day of that month.

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

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.

6. Contents of the pack and other information

What <INVENTED NAME> contains

- The active substance is buprenorphine.
- 0.2 mg: white to off-white, round, biconvex tablets and debossed with "I" on one side, with a diameter of approximately 5 mm.
  Each sublingual tablet contains 0.2 mg buprenorphine (equivalent to 0.216 mg buprenorphine hydrochloride).

- 0.4 mg tablets: white to off-white, round, biconvex tablets, and plane on both sides, with a diameter of approximately 5 mm.
  Each sublingual tablet contains 0.4 mg buprenorphine (equivalent to 0.432 mg buprenorphine hydrochloride).

- The other ingredients are: lactose monohydrate, mannitol, maize starch, Povidone K30, citric acid monohydrate, sodium citrate, magnesium stearate.

What <INVENTED NAME> looks like and contents of the pack

The sublingual tablets are packed in blisters consisting of aluminium (base foil) laminated with aluminium sheets with 7, 10, 20, 28, 30, 50, 60, 70, 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally].

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