PACKAGE LEAFLET

Package leaflet: Information for the patient

[Product name] 2 mg/0.5 mg sublingual tablets
[Product name] 8 mg/2 mg sublingual tablets

Buprenorphine/naloxone

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 [Product name] is and what it is used for

[Product name] is used to treat dependence on opioid (narcotic) drugs such as heroin or morphine in drug addicts who have agreed to be treated for their addiction. [Product name] is used in adults and adolescents over 15 years of age, who are also receiving medical, social and psychological support.

2. What you need to know before you take [Product name]

Do not take [Product name]
- if you are allergic to buprenorphine, naloxone 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 taking naltrexone or nalmefene for the treatment of alcohol or opioid dependence.

Warnings and precautions
Talk to your doctor before taking [Product name] if you have:
- asthma or other breathing problems
- problems with your liver such as hepatitis
- low blood pressure
- recently suffered a head injury or brain disease
- a urinary disorder (especially linked to enlarged prostrate in men)
- any kidney disease
- thyroid problems
- adrenocortical disorder (e.g. Addison's disease)
- depression or other conditions that are treated with antidepressants.

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 [product name] 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 [product 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 [product 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 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 [product name]).

The use of these medicines together with [Product name] can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and [Product name]").

Important things to be aware of:

- An emergency unit should be contacted immediately in case of accidental ingestion or suspicion of ingestion.

- **Additional monitoring**
  You may be more closely monitored by your doctor if you are over the age of 65.

- **Misuse and abuse**
  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 (see section 5). **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 buprenorphine or have taken it in combination with other central nervous system depressants, such as alcohol, benzodiazepines (tranquilisers), or other opioids.
  This medicine may cause severe, possibly fatal, respiratory depression (reduced ability to breathe) in children and non-dependent people who accidentally or deliberately take it.

- **Withdrawal symptoms**

This medicine can cause opioid withdrawal symptoms if you take it too soon after taking opioids. You should leave at least 6 hours after you use a short-acting opioid (e.g. morphine, heroin) or at least 24 hours after you use a long-acting opioid such as methadone.

This medicine can also cause withdrawal symptoms if you stop taking it abruptly. See section 3 'stopping treatment'.

- **Liver damage**
  Liver damage has been reported after taking [Product name], especially when the medicine is misused. This could also be due to viral infections (e.g. 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** [Product name]**.**

- **Blood pressure**
  This medicine may cause your blood pressure to drop suddenly, causing you to feel dizzy if you get up too quickly from sitting or lying down.

- **Sleep-related breathing disorders**
  [Product name] 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.

- **Diagnosis of unrelated medical conditions**
  This medicine may mask pain symptoms that could assist in the diagnosis of some diseases. You must tell your doctor that you take this medicine.

Children and adolescents
Do not give this medicine to **children under the age of 15.** If you are between 15 and 18 years old your doctor may monitor you more closely during treatment, because of the lack of data in this age group.

[To be completed nationally: [Product name] may cause a positive reaction in tests conducted during anti-doping checks.
Please note that [Product name] contains buprenorphine, which may give positive results in a doping test.]

Other medicines and [**Product name**]
Tell your doctor if you are taking, have recently taken or might take any other medicines.
Some medicines may increase the side effects of [Product name], these can be serious. Do not take any other medicines whilst taking [Product name] without first talking to your doctor, especially:

- Concomitant use of [Product name] and sedative medicines such as **benzodiazepines** (used to treat anxiety or sleep disorders) such as diazepam, temazepam, alprazolam 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 [Product name] 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 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 may 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
  - anti-depressants (used to treat depression) such as isocarboxazid, 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.

- clonidine (used to treat high blood pressure) may extend the effects of this medicine.
- anti-retrovirals (used to treat HIV) such as ritonavir, nelfinavir, indinavir may increase the effects of this medicine.
- some antifungal agents (used to treat fungal infections) such as ketoconazole, itraconazole, certain antibiotics, may extend the effects of this medicine.
- some medicines may decrease the effect of [Product name]. These include medicines used to treat epilepsy (such as carbamazepine and phenytoin), and medicines used to treat tuberculosis (rifampicin).
- Naltrexone and nalmefene (drugs used to treat addiction disorders) may prevent the therapeutic effects of [Product name]. They should not be taken at the same time as [Product name] treatment because you may experience a sudden onset of prolonged and intense withdrawal.
- medicines to treat depression such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with [Product name] 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.

[Product name] with food, drink and alcohol
Do not have alcohol whilst being treated with this medicine. Alcohol may increase drowsiness and may increase the risk of respiratory failure if taken with [Product name]. Do not swallow or consume food or any 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 for advice before taking this medicine.

The risks of using [**Product name**] in pregnant women are not known. Your doctor will decide if your treatment should be continued with an alternative medicine.

When taken during pregnancy, particularly late pregnancy, medicines like [Product name] may cause drug withdrawal symptoms including problems with breathing in your newborn baby. This may appear several days after birth.

Do not breast-feed whilst taking this medicine, since buprenorphine passes into breast milk.

Driving and using machines
Do not drive, cycle, use any tools or machines, or perform dangerous activities until you know how this medicine affects you. [Product name] may cause drowsiness, dizziness or impair your thinking. This may happen more often in the first few weeks of treatment when your dose is being changed, but it can also happen if you drink alcohol or take other sedative medicines at the same time as when you take [Product name].

[Product name] contains lactose and sodium

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 tablet, that is to say essentially 'sodium-free'.

3. How to take [Product name]

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 treatment is prescribed and monitored by doctors who are experienced in the treatment of drug dependence.
Your doctor will determine the best dose for you. During your treatment, the doctor may adjust the dose, depending upon your response.

Starting treatment

The recommended starting dose for adults and adolescents over the age of 15 years is usually two [Product name] 2 mg/0.5 mg sublingual tablets.

This dose may be repeated to twice on day 1 depending on your needs.

You should be aware of the clear signs of withdrawal before taking your first dose of [Product name]. Your doctor will tell you when to take your first dose.

- Starting treatment of [Product name] whilst **dependent on heroin**

  If you are dependent upon heroin or a short acting opioid, your first dose should be taken when signs of withdrawal appear, **at least 6 hours after you last used opioids.**

- Starting treatment of [Product name] whilst **dependent on methadone**

  If you have been taking methadone or a long acting opioid, the dose of methadone should ideally be reduced to below 30 mg/day before beginning [Product name] therapy. The first dose of [Product name] should be taken when signs of withdrawal appear, and at **least 24 hours after you last used methadone.**

Taking [Product name]
- Take the dose once a day by placing the tablets under the tongue.
- Keep the tablets in place under the tongue until they have **completely dissolved**. This may take 5-10 minutes.
- Do not chew or swallow the tablets, as the medicine will not work and you may get withdrawal symptoms.
- Do not consume any food or drink until the tablets have completely dissolved.

Dosage adjustment and maintenance therapy:
During the days after you start treatment, your doctor may increase the dose of [Product name] you take according to your needs. If you think that the effect of [Product name] is too strong or too weak, talk to your doctor or pharmacist. **The maximum daily dose is 24 mg buprenorphine.**

After a time of successful treatment, you may agree with your doctor to reduce the dose gradually to a lower maintenance dose.

Stopping treatment
Depending on your condition, the dose of [Product name] may continue to be reduced under careful medical supervision, until eventually it may be stopped.

Do not change the treatment in any way or stop treatment without the agreement of the doctor who is treating you.

If you take more [Product name] 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 for treatment as **overdose** with [Product name] may cause serious and life-threatening breathing problems.
Symptoms of overdose may include feeling sleepy and uncoordinated with slowed reflexes, blurred vision, and/or slurred speech. You may be unable to think clearly, and may breathe much slower than is normal for you.

If you forget to take [Product name]
Tell your doctor as soon as possible if you miss a dose.

If you stop taking [Product name]
Do not change the treatment in any way or stop treatment without the agreement of the doctor who is treating you. **Stopping treatment suddenly may cause withdrawal symptoms.**

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:
- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, severe hives/nettle rash. These may be signs of a life-threatening allergic reaction.
- feeling sleepy and uncoordinated, have blurred vision, have slurred speech, cannot think well or clearly, or your breathing gets much slower than is normal for you.

Also tell your doctor immediately if you experience side effects such as:
- severe tiredness, itching with yellowing of skin or eyes. These may be symptoms of liver damage.
- seeing or hearing things that are not there (hallucinations).

Side effects reported with [Product name]
Very common side effects (may effect more than one in 10 people):
Insomnia (inability to sleep), constipation, nausea, excessive sweating, headache, drug withdrawal syndrome.
Common side effects (may effect up to 1 in 10 people):
Weight loss, swelling (hands and feet), drowsiness, anxiety, nervousness, tingling, depression, decreased sexual drive, increase in muscle tension, abnormal thinking, increased tearing (watering eyes) or other tearing disorder, blurred vision, flushing, increased blood pressure, migraines, runny nose, sore throat and painful swallowing, increased cough, upset stomach or other stomach discomfort, diarrhoea, abnormal liver function, flatulence, vomiting, rash, itching, hives, pain, joint pain, muscle pain, leg cramps (muscle spasm), difficulty in getting or keeping an erection, urine abnormality, abdominal pain, back pain, weakness, infection, chills, chest pain, fever, flu-like symptoms, feeling of general discomfort, accidental injury caused by loss of alertness or co-ordination, faintness and dizziness.
Uncommon side effects (may effect up to 1 in 100 people):
Swollen glands (lymph nodes), agitation, tremor, abnormal dream, excessive muscle activity, depersonalisation (not feeling like yourself), medicine dependence, amnesia (memory disturbance), loss of interest, exaggerated feeling of well-being, convulsion (fits), speech disorder, small pupil size, difficulty urinating, eye inflammation or infection, rapid or slow heartbeat, low blood pressure, palpitations, heart attack, chest tightness, shortness of breath, asthma, yawning, pain and sores in mouth, tongue discolouration, acne, skin nodule, hair loss, dry or scaling skin, inflammation of joints, urinary tract infection, abnormal blood tests, blood in urine, abnormal ejaculation, menstrual or vaginal problems, kidney stone, protein in

your urine, painful or difficult urination, sensitivity to heat or cold, heat stroke, loss of appetite, feelings of hostility.
Not known (frequency cannot be estimated from the available data):
Sudden withdrawal syndrome caused by taking [**Product name**] too soon after use of illicit opioids, drug withdrawal syndrome in new-born babies, slow or difficult breathing, liver injury with or without jaundice, hallucinations, swelling of face and throat or life threatening allergic reactions, drop in blood pressure on changing position from sitting or lying down to standing, dental caries.

Misusing this medicine by injecting it can cause withdrawal symptoms, infections, other skin reactions and potentially serious liver problems (see Warnings and precautions)

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 [**Product name**]

Keep this medicine out of the sight and reach of children and other household members.

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

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.

[**Product name**] can be a target for people who abuse prescription medicine. Keep this medicine in a safe place to protect it from theft.

Store the blister safely.
Do not store above 30°C.
Never open the blister in advance.
Do not take this medicine in front of children.
An emergency unit should be contacted immediately in case of accidental ingestion or suspicion of ingestion.

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 [Product name] contains

- The active substances are buprenorphine and naloxone.
  Each 2 mg/0.5 mg sublingual tablet contains 2 mg buprenorphine (as hydrochloride) and 0.5 mg naloxone (as hydrochloride dihydrate).

  Each 8 mg/2 mg sublingual tablet contains 8 mg buprenorphine (as hydrochloride) and 2 mg naloxone (as hydrochloride dihydrate).
- The other ingredients are lactose monohydrate, mannitol, maize starch, povidone (K = 29.7), citric acid monohydrate, sodium citrate, magnesium stearate, acesulfame potassium, lemon flavour (contains: flavouring preparations, maltodextrin, Acacia), lime flavour (contains: flavouring preparations, maltodextrin, Acacia).

What [Product name] looks like and contents of the pack

[Product name] are white to off-white, round and biconvex sublingual tablets, with score line on one side. The tablet can be divided into equal doses.

The tablets are packaged in blisters in cardboard boxes containing 7 or 28 tablets or in unit-dose blisters of 7x1 or 28x1 tabletes.>

Not all pack sizes may be marketed.

Marketing Authorisation Holder
[To be completed nationally]

Manufacturer
G.L. Pharma GmbH
Schlossplatz 1, 8502 Lannach, Austria

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Denmark	Buprenorfin/Naloxon “Viatris”
Finland	Buprenorphine/Naloxone Viatris 2 mg/0,5 mg resoribletti
	Buprenorphine/Naloxone Viatris 8 mg/2 mg resoribletti
France:	BUPRENORPHINE/NALOXONE VIATRIS 2 mg/0,5 mg, comprimé sublingual
	BUPRENORPHINE/NALOXONE VIATRIS 8 mg/2 mg, comprimé sublingual
Italy	Buprenorfina e Naloxone Mylan Pharma
Netherlands	Buprenorfine/Naloxon Viatris 2 mg/0,5 mg, tabletten voor sublinguaal gebruik
	Buprenorfine/Naloxon Viatris 8 mg/2 mg, tabletten voor sublinguaal gebruik
Sweden:	Buprenorphine/Naloxone Viatris
United Kingdom	Buprenorphine/Naloxone Mylan 2 mg/0.5 mg sublingual tablets
(Northern Ireland)	Buprenorphine/Naloxone Mylan 8 mg/2 mg sublingual tablets

[To be completed nationally]

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.

[To be completed nationally]

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