Package leaflet: Information for the patient

Buprefarm 5 microgram/hour transdermal patch
Buprefarm 10 microgram/hour transdermal patch
Buprefarm 15 microgram/hour transdermal patch
Buprefarm 20 microgram/hour transdermal patch
Buprefarm 25 microgram/hour transdermal patch
Buprefarm 30 microgram/hour transdermal patch
Buprefarm 40 microgram/hour transdermal patch

buprenorphine

Read all of this leaflet carefully before you start using 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 Buprefarm is and what it is used for

Buprefarm contain the active ingredient buprenorphine which belongs to a group of medicines called strong analgesics or 'painkillers'. They have been prescribed for you by your doctor to relieve moderate, long-lasting pain that requires the use of a strong painkiller.

Buprefarm should not be used to relieve acute pain.

2. What you need to know before you use Buprefarm

Do not use Buprefarm:
- if you are allergic to buprenorphine or any of the other ingredients of this medicine (listed in section 6);
- if you have breathing problems;
- if you are addicted to drugs;
- if you are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromide, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks;
- if you suffer from myasthenia gravis (a condition in which the muscles become weak);
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking alcohol.

Buprefarm must not be used to treat symptoms associated with drug withdrawal.

Warnings and precautions
Talk to your doctor or pharmacist before using Buprefarm:
- if you suffer from seizures, fits or convulsions;

- if you suffer from sleep-related breathing disorder (sleep apnoea);
- if you have a severe headache or feel sick due to a head injury or increased pressure in your
- skull (for instance due to brain disease). This is because the patches may make symptoms worse or hide the extent of a head injury;
- if you are feeling light-headed or faint;
- if you have severe liver problems;
- if you have ever been addicted to drugs or alcohol;
- if you have a high temperature, as this may lead to larger quantities of the active ingredient being absorbed into the blood than normal;
- if you have depression or other conditions that are treated with antidepressants. The use of these medicines together with Buprefarm can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Buprefarm").

If you have recently had an operation, please speak to your doctor before using these patches. Similar to other opioids, Buprefarm patches may affect the normal production of hormones in the body, such as cortisol or sex hormones, particularly if you have taken high doses for long period of time.

Sleep-related breathing disorders
Buprefarm 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 Buprefarm 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 Buprefarm 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 Buprefarm, 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 Buprefarm).

Children and adolescents
Do not give this medicine to children and adolescents below 18 years.

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

- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).
- Buprefarm must not be used together with a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromide, phenelzine, isocarboxazid, moclobemide and linezolid), or if you have taken this type of medicine in the last two weeks.
- If you take some medicines such as phenobarbital or phenytoin (medicines commonly used to treat seizures, fits or convulsions), carbamazepine (a medicine to treat seizures, fits or convulsions and certain pain conditions), or rifampicin (a medicine to treat tuberculosis) the effects of Buprefarm may be reduced.
- Buprefarm may make some people feel drowsy, sick or faint or make them breathe more slowly or weakly. These side effects may be made worse if other medicines that produce the same effects are taken at the same time. These include certain medicines to treat pain, depression, anxiety, psychiatric or mental disorders, medicines to help you sleep, medicines to treat high blood pressure such as clonidine, other opioids (which may be found in painkillers or certain cough mixtures e.g. morphine, dextropropoxyphene, codeine, dextromethorphan, noscapine), antihistamines which make you drowsy, or anaesthetics such as halothane.
- Concomitant use of Buprefarm and sedative medicines such as benzodiazepines or related drugs may increase 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 Buprefarm 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.
- 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
- Anti-depressants such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with Buprefarm 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.

Buprefarm with alcohol
Alcohol may make some of the side effects worse and you may feel unwell if you drink alcohol whilst wearing Buprefarm. Drinking alcohol whilst using Buprefarm may also affect your reaction time.

Pregnancy, breast-feeding and fertility
You should not use Buprefarm if you are pregnant or are breast-feeding, think you may be pregnant or are planning to have a baby, unless otherwise instructed by your doctor having carefully considered the benefits and risk to both the mother and the child.

Ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines
Buprefarm may affect your reactions to such an extent that you may not react adequately or quickly

enough in the event of unexpected or sudden occurrences. This applies particularly:
- at the beginning of treatment;
- if you are taking medicines to treat anxiety or help you sleep;
- if your dose is increased.

If you are affected (e.g. feel dizzy, drowsy or have blurred vision), you should not drive or operate machinery whilst using Buprefarm, or for 24 hours after removing the patch.

3. How to use Buprefarm

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Buprefarm, 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 Buprefarm).

Different strengths of Buprefarm are available. Your doctor will decide which strength of Buprefarm will suit you best.

During treatment, your doctor may change the patch you use to a smaller or larger one if necessary, or tell you to use a combination of up to two patches. Do not cut or divide the patch or use a higher dose than recommended. You should not apply more than two patches at the same time, up to a maximum total dose of 40 micrograms/hour.

If you feel that the effect of the Buprefarm is too weak or too strong, talk to your doctor or pharmacist.

Adults and elderly patients
Unless your doctor has told you differently, attach one Buprefarm patch (as described in detail below) and change it every seventh day, preferably at the same time of day. Your doctor may wish to adjust the dose after 3-7 days until the correct level of pain control has been found. If your doctor has advised you to take other painkillers in addition to the patch, strictly follow the doctor's instructions, otherwise you will not fully benefit from treatment with Buprefarm. The patch should be worn for 3 full days before increasing the dose, this is when the maximum effect of a given dose is established.

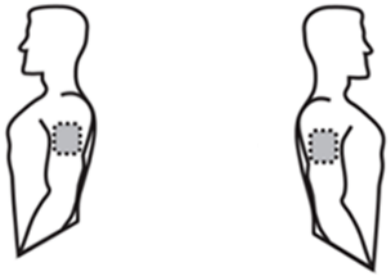
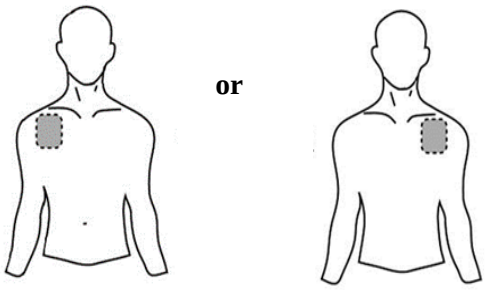
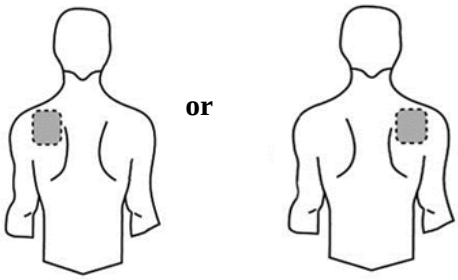
Patients with kidney disease/dialysis patients
In patients with kidney disease, no change in dose is necessary.

Patients with liver disease
In patients with liver disease, the effects and period of action of the Buprefarm may be affected and your doctor will therefore check on you more closely.

Patients under 18 years of age
Buprefarm should not be used in patients below the age of 18 years.

Method of administration
Buprefarm transdermal patch is for transdermal use.
Buprefarm act through the skin. After application, buprenorphine passes through the skin into the blood.

Before applying the transdermal patch

- Choose an area of non-irritated, intact skin on your upper arm, outer arm, upper chest, upper back or side of the chest. (See illustrations besides). Ask for assistance if you cannot apply the patch yourself.	**Upper Arm** **or**  **Front**  **Back** 

- The Buprefarm patch should be applied to a relatively hairless or nearly hairless skin site. If no suitable hair free sites are available the hairs should be cut off with a pair of scissors. Do not shave them off.

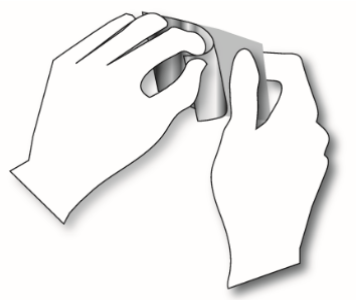
- Avoid skin which is red, irritated or has any other blemishes, for instance large scars.

- The area of skin you choose must be dry and clean. If necessary, wash it with cold or lukewarm water. Do not use soap, alcohol, oil, lotions or other detergents. After a hot bath or shower, wait until your skin is completely dry and cool. Do not apply lotion, cream or ointment to the chosen area. This might prevent your patch from sticking properly.

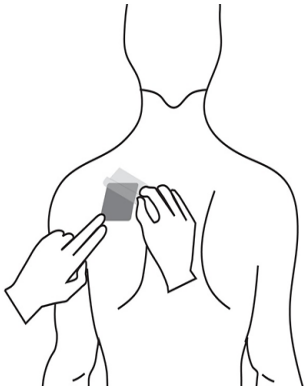
Applying the transdermal patch

- Step 1: Each transdermal patch is sealed in a sachet. Just before use, cut the sachet along the sealed edge with scissors. Take out the transdermal patch. Do not use the patch if the sachet seal is broken.

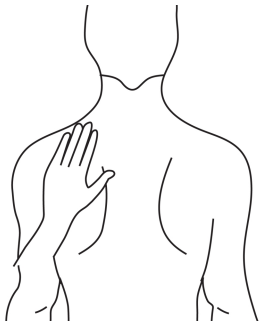
- Step 2: The sticky side of the transdermal patch is covered with a transparent protective foil. Carefully peel off **one part of** the foil. Try not to touch the sticky part of the transdermal patch.



- Step 3: Stick the transdermal patch on to the area of skin you have chosen and remove the remaining foil.



- Step 4: Press the transdermal patch against your skin with the palm of your hand and count slowly to 30. Make sure that the whole transdermal patch is in contact with your skin, especially at the edges.



Wearing the transdermal patch

You should wear the patch for seven days. Provided that you have applied the patch correctly, there is little risk of it coming off. If the edges of the patch begin to peel off, they may be taped down with a suitable skin tape. You may shower, bathe or swim whilst wearing it.

Do not expose the patch to extreme heat (e.g. heating pads, electric blanket, heat lamps, sauna, hot tubs, heated water beds, hot water bottle, etc) as this may lead to larger quantities of the active ingredient being absorbed into the blood than normal. External heat may also prevent the patch from sticking properly. If you have a high temperature this may alter the effects of Buprefarm (see "Warnings and precautions" section above).

In the unlikely event that your patch falls off before it needs changing, do not use the same patch again. Stick a new one on straight away (see “Changing the transdermal patch” below).

Changing the transdermal patch

- Take the old transdermal patch off.
- Fold it in half with the sticky side inwards.
- Open and take out a new patch. Use the empty sachet to dispose of the old patch. Now discard the sachet safely.
- Stick a new transdermal patch on a different appropriate skin site (as described above). You should not apply a new patch to the same site for 3-4 weeks.
- Remember to change your patch at the same time of day. It is important that you make a note of the time of day.

Duration of treatment
Your doctor will tell you how long you should be treated with the Buprefarm. Do not stop treatment without consulting a doctor, because your pain may return and you may feel unwell (see also “If you stop using Buprefarm” below).

If you use more Buprefarm than you should
As soon as you discover that you have used more patches than you should, remove all patches and call your doctor or hospital straight away. People who have taken an overdose may feel very sleepy and sick. They may also have breathing difficulties or lose consciousness and may need emergency treatment in hospital. When seeking medical attention make sure that you take this leaflet and any remaining patches with you to show to the doctor.

If you forget to use Buprefarm
Stick a new patch on as soon as you remember. Also make a note of the date, as your usual day of changing may now be different. If you are very late changing your patch, your pain may return. In this case, please contact your doctor.

Do not apply additional patches to make up for the forgotten application.

If you stop using Buprefarm
If you stop using Buprefarm too soon or you interrupt your treatment your pain may return. If you wish to stop treatment please consult your doctor. They will tell you what can be done and whether you can be treated with other medicines.

Some people may have side effects when they have used strong painkillers for a long time and stop using them. The risk of having effects after stopping Buprefarm is very low. However, if you feel agitated, anxious, nervous or shaky, if you are overactive, have difficulty sleeping or digestive problems, tell your doctor.

The pain relieving effect of Buprefarm is maintained for some time after removal of the patch. You should not start another opioid analgesic (strong painkiller) within 24 hours after removal of the patch.

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.

Serious side effects that may be associated with Buprefarm are similar to those seen with other strong painkillers and include difficulty in breathing and low blood pressure.

This medicine can cause allergic reactions, although serious allergic reactions are rare. Remove the patch and tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.

There is a risk that you may become addicted or reliant on Buprefarm.

In patients treated with buprenorphine, the following other side effects have been reported:

Very common (may affect more than 1 in 10 people):
- Headache, dizziness, drowsiness.
- Constipation, feeling or actually being sick.
- Itchy skin.
- Rash, redness, itching, inflammation or swelling of the skin at the application site.

Common (may affect up to 1 in 10 people):
- Loss of appetite.
- Confusion, depression, anxiety, difficulty in sleeping, nervousness, shaking (tremors).
- Shortness of breath.
- Abdominal pain or discomfort, diarrhoea, indigestion, dry mouth.
- Sweating, rash, skin eruptions.
- Tiredness, a feeling of unusual weakness, muscle weakness, swelling of hands, ankles or feet.

Uncommon (may affect up to 1 in 100 people):
- Restlessness, agitation, a feeling of extreme happiness, hallucinations, nightmares, decreased sexual drive, aggression.
- Changes in taste, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness.
- Loss of memory, migraine, fainting, problems with concentration or co-ordination.
- Dry eyes, blurred vision.
- A ringing or buzzing sound in the ears, a feeling of dizziness or spinning.
- High or low blood pressure, chest pain, fast or irregular heartbeat.
- Cough, hiccups, wheezing.
- Wind.
- Weight loss.
- Dry skin.
- Spasms, aches and pains.
- Difficulty in beginning the flow of urine.
- Inability to fully empty the bladder.
- Urinary incontinence.
- Fever.
- An increase in accidental injuries (e.g. falls).
- Withdrawal symptoms such as agitation, anxiousness, sweating or shaking upon stopping using Buprefarm.
- Dermatitis contact (skin rash with inflammation which may include burning sensation).

If you need to have blood tests remind your doctor that you are using Buprefarm. This is important because Buprefarm may change the way your liver works and this could affect the results of some blood tests.

Rare (may affect up to 1 in 1,000 people):
- Angina (chest pain associated with heart disease).
- Mental disorder.
- Difficulties with balance.
- Swelling of the eyelids or face, a reduction in size of the pupils in the eye.
- Difficulty in breathing, worsening of asthma, over breathing.
- A feeling of faintness, especially on standing up.
- Difficulty in swallowing.
- Local allergic reaction with marked signs of swelling (in such cases treatment should be stopped).
- Swelling and irritation inside the nose.
- Decreased erection, sexual dysfunction.

- A flu like illness.
- Flushing of the skin.
- Dehydration.

Very rare (may affect up to 1 in 10,000 people):
- Muscle twitching.
- Mood swings.
- Ear pain.
- Blisters.

Not known (frequency cannot be estimated from the available data):
- Problems with breathing during sleep (sleep apnoea syndrome), see section 2 "Warnings and precautions."
- Seizures, fits or convulsions.
- Inflammation of the bowel wall. Symptoms may include fever, vomiting and stomach pain or discomfort.
- Colicky abdominal pain or discomfort.
- Feeling detached from oneself.
- Withdrawal symptoms in babies born to mothers who have been given buprenorphine during pregnancy may include high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties, sweating and not putting on weight.
- Skin discolouration.

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 Buprefarm

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 sachet after EXP. 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.

5, 10 and 15 microgram/h patches: Do not store above 25°C.

20, 25, 30 and 40 microgram/h patches: This medicine does not require any special storage conditions.

Do not use the patch if the sachet seal is broken.

Used patches must be folded over on themselves with the adhesive layer inwards, and discarded safely.

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 Buprefarm patches contain
- The active substance is buprenorphine.

Buprefarm 5 microgram/hour: Each transdermal patch contains 5 mg of buprenorphine in a patch size of 6.25 cm^2 and releases 5 micrograms of buprenorphine per hour (over a period of 7 days).
Buprefarm 10 microgram/hour: Each transdermal patch contains 10 mg of buprenorphine in a patch size of 12.5 cm^2 and releases 10 micrograms of buprenorphine per hour (over a period of 7 days).
Buprefarm 15 microgram/hour: Each transdermal patch contains 15 mg of buprenorphine in a patch size of 18.75 cm2 and releases 15 micrograms of buprenorphine per hour (over a period of 7 days).
Buprefarm 20 microgram/hour: Each transdermal patch contains 20 mg of buprenorphine in a patch size of 25 cm^2 and releases 20 micrograms of buprenorphine per hour (over a period of 7 days).
Buprefarm 25 microgram/hour: Each transdermal patch contains 25 mg of buprenorphine in a patch size of 31.25 cm^2 and releases 25 micrograms of buprenorphine per hour (over a period of 7 days).
Buprefarm 30 microgram/hour: Each transdermal patch contains 30 mg of buprenorphine in a patch size of 37.5 cm^2 and releases 30 micrograms of buprenorphine per hour (over a period of 7 days).
Buprefarm 40 microgram/hour: Each transdermal patch contains 40 mg of buprenorphine in a patch size of 50 cm^2 and releases 40 micrograms of buprenorphine per hour (over a period of 7 days).

- The other ingredients are:
  Adhesive matrix (containing buprenorphine): povidone, levulinic acid, oleyl oleate, Poly[acrylic acid-co-butylacrylate-co-(2-ethylhexyl)acrylate-co-vinylacetate],
  Adhesive matrix (without buprenorphine): Poly[(2-ethylhexyl)acrylate-co-glycidylmethacrylate-co-(2-hydroxyethyl)acrylate-co-vinylacetate],
  Separating foil between adhesive matrices with and without buprenorphine: Polyethylene terephthalate film,
  Backing foil: polyester,
  Release liner: Polyethylene terephthalate film, siliconised
  Blue printing ink.

What Buprefarm look like and contents of the pack
Transdermal patch
Seven sizes are available.
Buprefarm 5 microgram/hour: Each transdermal patch is beige coloured with rounded corners and is imprinted with “Buprenorphin” and “5 µg/h”
Buprefarm 10 microgram/hour: Each transdermal patch is beige coloured with rounded corners and is imprinted with “Buprenorphin” and “10 µg/h”
Buprefarm 15 microgram/hour: Each transdermal patch is beige coloured with rounded corners and is imprinted with “Buprenorphin” and “15 µg/h”
Buprefarm 20 microgram/hour: Each transdermal patch is beige coloured with rounded corners and is imprinted with “Buprenorphin” and “20 µg/h”
Buprefarm 25 microgram/hour: Each transdermal patch is beige coloured with rounded corners and is imprinted with “Buprenorphin” and “25 µg/h”
Buprefarm 30 microgram/hour: Each transdermal patch is beige coloured with rounded corners and is imprinted with “Buprenorphin” and “30 µg/h”
Buprefarm 40 microgram/hour: Each transdermal patch is beige coloured with rounded corners and is imprinted with “Buprenorphin” and “40 µg/h”

One transdermal patch is sealed in one child-resistant sachet. The patches are available in cartons containing 1, 2, 3, 4, 5, 8, 10 or 12 transdermal patches.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
[to be completed nationally]

Manufacturer
[to be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:
Denmark, Finland, Norway, Sweden: Buprefarm

This leaflet was last revised in 23 Oct 2024

<Detailed information on this medicine is available on the web site of {MA/Agency}>