Package leaflet: Information for the user

[Nationally completed name] 35 micrograms/h transdermal patch
[Nationally completed name] 52.5 micrograms/h transdermal patch
[Nationally completed name] 70 micrograms/h 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 [Nationally completed name] is and what it is used for

The active substance of [Nationally completed name] is buprenorphine.

[Nationally completed name] is an analgesic (a pain-relieving medicine) intended to relieve moderate to severe cancer pain and severe pain that has not responded to other types of painkillers. [Nationally completed name] acts through the skin. Buprenorphine is an opioid (strong pain reliever), which reduces pain by acting on the central nervous system (specific nerve cells in the spinal cord and in the brain). The effect of the transdermal patch lasts for up to four days. [Nationally completed name] is not suitable for the treatment of acute (short-lasting) pain.

2. What you need to know before you use [Nationally completed name]

Do not use [Nationally completed name] if you:
- are allergic to buprenorphine or any of the other ingredients of this medicine (listed in section 6);
- are dependent on strong pain relievers (opioids);
- suffer from a disease in which you have or may have great difficulty breathing
- are taking monoamine oxidase (MAO) inhibitors (certain medicines used to treat depression) or you have taken this type of medicine in the last two weeks (see " Other medicines and [Nationally completed name]");

- suffer from myasthenia gravis (a certain type of severe muscle weakness);
- suffer from delirium tremens (confusion and trembling caused by abstinence from alcohol following habitual excessive drinking or occurring during an episode of heavy alcohol consumption);
- are pregnant.

[Nationally completed name] must not be used to treat withdrawal symptoms in drug-dependent persons.

Warnings and precautions
Talk to your doctor or pharmacist before using [Nationally completed name]
- if you have recently drunk a lot of alcohol;
- if you suffer from seizures or convulsions (fits)
- if your consciousness is disturbed (feeling light-headed or faint) for an unknown reason;
- if you are in a state of shock (cold sweat might be a sign of it);
- if the pressure in your skull is increased (for instance after head injury or in brain disease), and artificial respiration is not possible;
- if you have difficulty breathing or are taking other medicines that may make you breathe more slowly or weakly (see " Other medicines and [Nationally completed name]");
- if your liver does not work properly;
- if you are inclined to abuse medicines or drugs.

Sleep-related breathing disorders
[Nationally completed name] contains an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example central sleep apnoea (shallow/pause of breathing during sleep) and sleep-related hypoxemia (low level of oxygen in the blood). The risk of experiencing central sleep apnoea is dependent on the dose of opioids. Your doctor may consider decreasing your total opioid dose if you experience central sleep apnoea.

Also, please be aware of the following precautions:
- Some people may become dependent on strong pain relievers such as [Nationally completed name] when they use them over a long period of time. They may have withdrawal effects when they stop using them (see "If you stop using [Nationally completed name]").
- Fever and external heat may lead to larger quantities of buprenorphine in the blood than normal. Also, external heat may prevent the transdermal patch from sticking properly. Therefore, do not expose yourself to external heat (e.g. sauna, infra-red lamps, electric blankets, hot water bottles) and consult your doctor if you have fever.

Athletes should be aware that this medicine may cause a positive reaction to sports doping control tests.

Children and adolescents
[Nationally completed name] should not be used in children and adolescents below the age of 18 years, because no experience has so far been gained in this age group.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- [Nationally completed name]must not be used together with monoamine oxidase (MAO) inhibitors (certain medicines used to treat depression), or if you have taken this type of medicine for the last 2 weeks.
- [Nationally completed name] may make some people feel drowsy, sick, or faint or make them breathe more slowly or weakly. These side effects may be intensified if other medicines that may produce the same effects are taken at the same time. These other medicines include other strong pain relievers (opioids), certain sleeping pills, anaesthetics, and medicines used to treat certain psychological diseases such as tranquillizers, anti-depressants, and neuroleptics. Concomitant use of [Nationally completed name] and sedative medicines such as benzodiazepines or related medicines 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 [Nationally completed name] together with sedative medicines the dose and the 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
- If [Nationally completed name] is used together with some medicines, the effects of the transdermal patch may be increased. These medicines include e.g. certain anti-infectives/anti-fungals (e.g. containing erythromycin or ketoconazole) or HIV medicines (e.g. containing ritonavir)
- If [Nationally completed name] is used together with other medicines, the effects of the transdermal patch may be reduced. These medicines include certain products, e.g. dexamethasone; medicines to treat epilepsy (e.g. containing carbamazepine, or phenytoin) or medicines for tuberculosis (e.g. rifampicin).

[Nationally completed name] with food, drink and alcohol

You should not drink alcohol while using [Nationally completed name]. Alcohol may intensify certain side effects of the transdermal patch and you may feel unwell.

Pregnancy, breast-feeding and fertility
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 using this medicine.

- **pregnancy**
  There is insufficient experience regarding the use of [Nationally completed name] in pregnant women. Therefore, you must not use [Nationally completed name] during pregnancy.

- **breast-feeding**
  Buprenorphine, the active substance contained in the transdermal patch, inhibits milk formation and passes into the breast milk. Therefore, you should not use [Nationally completed name] if you are breast-feeding.

Driving and using machines
[Nationally completed name] may make you feel dizzy or drowsy or experience blurred or double vision and 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,

- when your dose is changed,
- when you switch to [Nationally completed name] from another pain reliever,
- if you also use other medicines that act on the brain,
- if you drink alcohol.

If you are affected, you should not drive or operate machinery whilst using [Nationally completed name]. This applies also at the end of treatment with [Nationally completed name]. Do not drive or operate machinery for at least 24 hours after the patch has been removed.

Discuss with your doctor or pharmacist if you are unsure about anything.

3. How to use [Nationally completed name]

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
[Nationally completed name] is available in three strengths: [Nationally completed name] 35 micrograms/h transdermal patch, [Nationally completed name] 52.5 micrograms/h transdermal patch and [Nationally completed name] 70 micrograms/h transdermal patch.

The choice of which strength of [Nationally completed name] will suit you best will be made by your doctor. During treatment your doctor may change which transdermal patch you use to a smaller or larger one if necessary.

The recommended dose is:

Adults
Unless your doctor has told you differently, attach one [Nationally completed name] transdermal patch (as described in detail below) and change it after 4 days at the latest. For convenience of use, you can change the transdermal patch twice a week at the same days, e.g. always on Monday mornings and Thursday evenings. To help you remember when to change your transdermal patch, you should make a note on the calendar on the outer packaging. If your doctor has advised you to take other pain relievers in addition to the transdermal patch, strictly follow the doctor's instructions, otherwise you will not fully benefit from treatment with [Nationally completed name].

Elderly patients
No dose adjustment is needed for elderly patients.

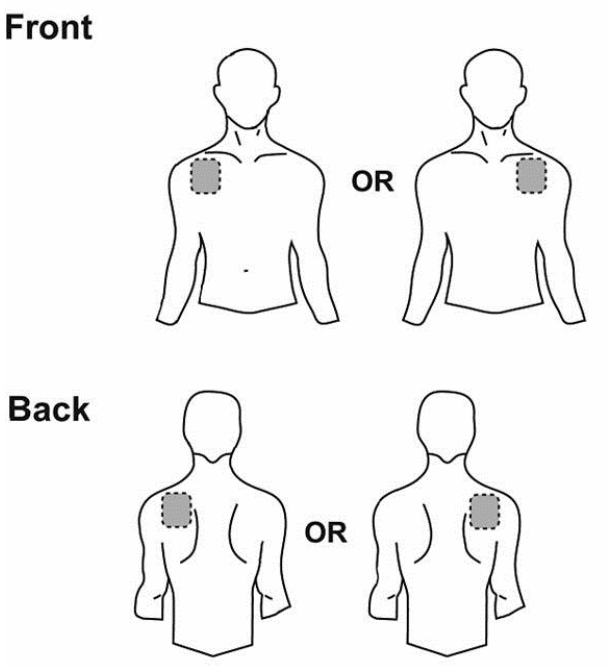
Patients with kidney disease / dialysis patients
In patients with kidney disease and in dialysis patients, no dose adjustment is necessary.

Patients with liver disease
In patients with liver disease, the intensity and duration of action of [Nationally completed name] may be affected. If this applies to you, your doctor will check on you more closely.

Use in children and adolescents
[Nationally completed name] should not be used in persons below the age of 18 years, because no experience has so far been gained in this age group.

Route of administration
The patch is for transdermal use.
When the transdermal patch is applied to the skin, the active substance buprenorphine passes through the skin into the blood.

Method of administration
Before applying the transdermal patch

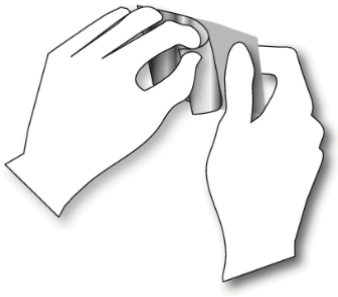
- Choose an area of skin which is flat, clean, free from cuts or scars and hairless on your upper body, preferably on the chest below the collar-bone or on the upper part of the back (see adjacent illustrations). Call assistance if you cannot apply the transdermal patch yourself.	

- If the chosen area has hairs, cut them 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 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 transdermal patch from sticking properly.

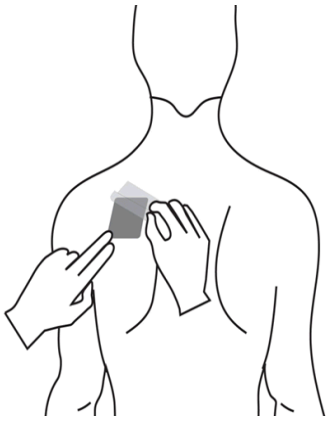
Applying the transdermal patch

- 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.

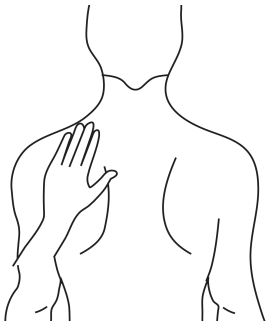
- Step 2: The sticky side of the transdermal patch is covered with a transparent protective foil. Carefully peel off **one part of** the foil. Try not to touch the sticky part of the transdermal patch.



- Step 3: Stick the transdermal patch onto 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 for about 30 to 60 seconds. Make sure that the whole transdermal patch is in contact with your skin, especially at the edges.



- Step 5: Wash your hands after using the transdermal

patch. Do not use any cleansing products.

Wearing the transdermal patch
You may wear the transdermal patch for up to 4 days. Provided that you have applied the transdermal patch correctly, there is little risk of it coming off. You may shower, bathe or swim while wearing it. However, do not expose the transdermal patch to extreme heat (e.g. sauna baths, infra-red lamps, electric blankets, hot water bottles).

In the unlikely event that your transdermal patch falls off before it needs changing, do not use the same transdermal 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.
- Throw it away carefully**.**
- Stick a new transdermal patch on a different skin site (as described above). Wait at least one week before using the same site again.

Duration of treatment
Your doctor will tell you how long you may use [Nationally completed name]. Do not stop using [Nationally completed name] on your own account, because pain may return and you may feel unwell (see also "If you stop using [Nationally completed name]" below).
If you have the impression that the effect of the [Nationally completed name] transdermal patch is too weak or too strong, tell your doctor or pharmacist.

If you use more [Nationally completed name] than you should
If this happens there may be signs of an overdose of the substance buprenorphine. An overdose may intensify the side effects of buprenorphine such as drowsiness, nausea, and vomiting. You may get pin-point pupils and breathing may become slow and weak. You may also get cardiovascular collapse.

As soon as you discover that you have used more transdermal patches than you should, remove the excess transdermal patches and talk to a doctor or pharmacist.

If you forget to use [Nationally completed name]
If you forget an application, stick a new transdermal patch on as soon as you remember. You will then need to change your routine, e.g. if you usually apply your transdermal patches on Mondays and Thursdays, but you forget and don't stick on a new transdermal patch until Wednesday, you will need to change your transdermal patches on Wednesdays and Saturdays from then on. Make a note of the new pair of days on the calendar on the outer packaging. If you are very late changing your transdermal patch, pain may return. In this case please contact your doctor.

Never apply twice the number of transdermal patches to make up for the forgotten application!

If you stop using [Nationally completed name]
If you interrupt or finish using [Nationally completed name] too soon, pain may return. If you wish to stop use on account of unpleasant side effects, please consult your doctor. He/she will tell you what can be done and whether you can be treated with other medicines.

Some people may experience withdrawal-effects when they have used strong pain relievers for a long time and stop using them. The risk of having effects after you stop using [Nationally completed name] is very low. However, if you feel agitated, anxious, nervous or shaky, if you are overactive, have difficulty sleeping or digestion problems, tell your doctor.

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.

If you experience swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, hives, fainting, yellowing of the skin and eyes (also called jaundice), remove the transdermal patch and call your doctor immediately or seek help at the casualty department of the nearest hospital. These can be symptoms of a very rare serious allergic reaction.

The following side effects have been reported:

Very common (may affect more than 1 in 10 people):
- nausea (feeling sick)
- redness, itching

Common (may affect up to 1 in 10 people):
- dizziness, headache
- shortness of breath
- vomiting, constipation
- skin changes (exanthema, generally on repeated use), sweating
- oedema (e.g. swelling of the legs), tiredness

Uncommon (may affect up to 1 in 100 people):
- confusion, sleep disorder, restlessness
- various degrees of sedation (calmness), ranging from tiredness to muzziness
- circulation disorders (such as low blood pressure or, rarely, even fainting)
- dry mouth
- rash
- difficulty in passing urine, urinary retention (less urine than normal)
- weariness

Rare (may affect up to 1 in 1,000 people):
- loss of appetite
- illusions such as hallucinations, anxiety and nightmares
- reduced sex drive
- difficulties concentrating, speech disorder, muzziness, disturbed balance, abnormal skin sensations (numbness, prickling or burning sensations)
- visual disturbance, blurred vision, swollen eyelids
- hot flushes

- difficulty breathing (respiratory depression)
- heartburn
- hives
- erection difficulties
- withdrawal symptoms (see below), administration site reactions

Very rare (may affect up to 1 in 10,000 people):
- serious allergic reactions (see below)
- dependence, mood swings
- muscle twitching, taste disorders
- pin-point pupils
- ear pain
- abnormally rapid breathing, hiccups
- retching
- pustules, small blisters
- chest pain

If you notice any of the side effects listed above, tell your doctor as soon as possible.

In some cases delayed allergic reactions occurred with marked signs of inflammation. In such a case you should stop using [Nationally completed name] after you have talked to your doctor. Some people may have withdrawal symptoms when they have used strong pain relievers for a long time and stop using them. The risk of having withdrawal effects when you stop using [Nationally completed name] is low. However, if you feel agitated, anxious, nervous or shaky, if you are overactive, have difficulty sleeping or digestion problems, tell your doctor.

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 [Nationally completed 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 sachet after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After removing a patch, fold it in half with the sticky sides inwards and press them together. Return the used patch to its sachet and carefully dispose the transdermal patch.

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 [Nationally completed name] contains

- The active substance is buprenorphine.

[35 micrograms /h:]

Each transdermal patch of 25 cm^2 contains 20 mg of buprenorphine and releases 35 micrograms of buprenorphine per hour.
[52.5 micrograms /h:]
Each transdermal patch of 37.5 cm^2 contains 30 mg of buprenorphine and releases 52.5 micrograms of buprenorphine per hour.
[70 micrograms /h:]
Each transdermal patch of 50 cm^2 contains 40 mg of buprenorphine and releases 70 micrograms of buprenorphine per hour.

- The other ingredients are:

Adhesive matrix (containing buprenorphine): povidone K90, levulinic acid, oleyl oleate, Poly[acrylic acid-co-butylacrylate-co-(2-ethylhexyl)acrylate-co-vinylacetate] (5:15:75:5)
Adhesive matrix (without buprenorphine): Poly[(2-ethylhexyl)acrylate-co-glycidylmethacrylate-co-(2-hydroxyethyl)acrylate-co-vinylacetate] (68:0,15:5:27),
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 [Nationally completed name] looks like and contents of the pack

Each transdermal patch is rectangular beige coloured with rounded corners and is imprinted
[35 µg/h:]
"Buprenorphin" and "35 µg/h"
[52.5 µg/h:]
"Buprenorphin" and "52.5 µg/h"
[70 µg/h:]
"Buprenorphin" and "70 µg/h"

Each transdermal patch is sealed in one child-resistant sachet. The patches are available in packs containing
[For DE/H/5083,4451/001-003/DC]
3, 4, 5, 6, 8, 10, 12, 16, 18, 20 or 24 transdermal patches.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

This leaflet was last revised in {MM/YYYY}.
[To be completed nationally]