Bijsluiter: Informatie voor de gebruiker

Buprenorfine Sandoz 25 microgram/uur 7 dagen, pleister voor transdermaal gebruik
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buprenorfine

For use in adults

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

{[Nationally completed name]} transdermal patches contain the active substance buprenorphine, which belongs to a group of medicines called strong analgesics or 'painkillers'.

{[Nationally completed name]} is used in adults to relieve moderate, long-lasting pain that requires the use of a strong painkiller.

{[Nationally completed name]} should not be used to relieve acute 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)
- have breathing problems
- are addicted to drugs

- are taking a type of medicine known as a monoamine oxidase (MAO) inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks
- suffer from myasthenia gravis (a condition in which the muscles become weak)
- suffer from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking alcohol

{[Nationally completed name]} must not be used to treat symptoms associated with drug withdrawal.

Warnings and precautions
Talk to your doctor or pharmacist before using {[Nationally completed name]} if you
- recently drunk a lot of alcohol
- suffer from seizures, fits or convulsions
- suffer from a breathing related sleep disorder (sleep apnoea)
- 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.
- are feeling light-headed or faint
- have severe liver problems
- or anyone in your family have ever abused or been dependent on alcohol prescription medicines or illegal drugs ("addiction")
- are a smoker
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses
- have a high temperature, as this may lead to larger quantities of the active substance being absorbed into the blood than normal
- are treated with antidepressants
  The use of these medicines together with {[Nationally completed name]} can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and {[Nationally completed name]}").
- suffer from constipation

This medicine may cause application site reactions which are usually presented by a mild or moderate skin inflammation, and their typical appearance may include redness, swelling, itching, rash, small blisters, and painful/burning sensation at the application site. Most commonly the cause is skin irritation, and these reactions stop after {[Nationally completed name]} patches are removed. More serious allergic reactions may occur such as blisters with discharge, which may spread outside the application site and may not resolve rapidly after {[Nationally completed name]} removal. Chronic allergic reactions may lead to open wounds, bleeding, ulcers, skin discoloration and infections. If you notice any of the above skin reactions, please contact your doctor.

This medicine may increase your sensitivity to pain particularly at high doses. Tell your doctor if this happens. A reduction in your dose or a change in your medicine may be necessary.

If you have recently had an operation, please speak to your doctor before using these transdermal patches.

Sleep-related breathing disorders: [Nationally completed 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.

{[Nationally completed name]} may affect the normal production of hormones in the body, such as cortisol or sex hormones, particularly if you have used high doses for a long period of time.

Athletes should be aware that this medicine may cause a positive reaction to sports doping control tests.
Use of {[Nationally completed name]} as a doping agent may become a health hazard.

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

Other medicines and {[Nationally completed 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 {[Nationally completed name]} and may sometimes cause very serious reactions.
Do not take any other medicines whilst using {[Nationally completed name]} without first talking to your doctor, especially:

- {[Nationally completed name]} must not be used together with a type of medicine known as a monoamine oxidase (MAO) inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or if you have taken this type of medicine in the last two weeks.
- Anti-depressants such as citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with {[Nationally completed 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.
- 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 {[Nationally completed name]} may be reduced.
- {[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 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 {[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 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.

{[Nationally completed name]} with alcohol
Alcohol may make some of the side effects worse and you may feel unwell if you drink alcohol whilst using {[Nationally completed name]}. Drinking alcohol whilst using {[Nationally completed name]} may also affect your reaction time.

Pregnancy and breast-feeding
You should not use {[Nationally completed name]} 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
{[Nationally completed name]} 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 {[Nationally completed name]}, or for 24 hours after removing the transdermal patch.

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.

Different strengths of {[Nationally completed name]} are available. Your doctor will decide which strength of buprenorphine transdermal patches will suit you best.

When people first start using buprenorphine transdermal patches, they often experience some nausea and vomiting (see section 4). This usually passes after the first week of treatment. It's a good idea to book a follow-up appointment with your doctor a week or two after you first start using {[Nationally completed name]} transdermal patches to ensure that you are taking the correct dose and to manage any side effects.

During treatment, your doctor may change the transdermal 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 transdermal patches at the same time up to a maximum total dose of 40 micrograms/hour**.

If you feel that the effect of {[Nationally completed name]} 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 {[Nationally completed name]} transdermal 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 transdermal patch, strictly follow the doctor's instructions, otherwise you will not fully benefit from treatment with {[Nationally completed name]}. The transdermal 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 liver disease
In patients with liver disease, the effects and period of action of {[Nationally completed name]} may be affected and your doctor will therefore check on you more closely.

Use in children and adolescents
{[Nationally completed name]} transdermal patches should not be used in patients below the age of 18 years.

Method of administration
{[Nationally completed name]} is for transdermal use.
{[Nationally completed name]} act through the skin. After application, buprenorphine passes through the skin into the blood.

Before applying {[Nationally completed name]} 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 below). Ask for assistance if you cannot apply the transdermal patch yourself.

- The buprenorphine transdermal 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 transdermal patch from sticking properly.

Applying the transdermal patch

Step 1: Each transdermal patch is sealed in a sachet. Just before use, open the sachet by tearing where indicated. Take out the transdermal patch. Do not use the transdermal patch if the sachet seal is broken.

Step 2: The sticky side of the transdermal patch is covered with a transparent foil. Carefully peel off half 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 transdermal patch for seven days**. Provided that you have applied the transdermal patch correctly, there is little risk of it coming off. If the edges of the transdermal 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 transdermal 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 substance being absorbed into the blood than normal. External heat may also prevent the transdermal patch from sticking properly. If you have a high temperature this may alter the effects of {[Nationally completed name]} (see "Warnings and precautions" section above).

In the unlikely event that your transdermal 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 transdermal patch. Use the empty sachet to dispose of the old transdermal patch. Now discard the sachet safely.
- Even used patches contain some active substance that may harm children or animals, so make sure your used patches are always kept out of the reach and sight of them.
- Stick a new transdermal patch on a different appropriate skin site (as described above). You should not apply a new transdermal patch to the same site for 3-4 weeks.
- Remember to change your transdermal 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 {[Nationally completed name]}. Do not stop treatment without consulting a doctor, because your pain may return and you may feel unwell (see also "If you stop using {[Nationally completed name]}" below).

If you use more {[Nationally completed name]} than you should
As soon as you discover that you have used more transdermal patches than you should, remove all transdermal 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 transdermal patches with you to show to the doctor.

If you forget to apply {[Nationally completed name]}
Stick a new transdermal 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 transdermal patch, your pain may return. In this case, please contact your doctor.

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

If you stop using {[Nationally completed name]}
If you stop using {[Nationally completed name]} 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 {[Nationally completed name]} 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 {[Nationally completed name]} is maintained for some time after removal of the transdermal patch. You should not start another opioid analgesic (strong painkiller) within 24 hours after removal of the transdermal 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 {[Nationally completed name]} 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 transdermal 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 {[Nationally completed name]}.

In patients treated with {[Nationally completed name]}, 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, redness of the skin
- rash, itching, redness, 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, oedema (e. g. 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 heartbeat, feeling your heartbeat, flushing
- cough, hiccups, wheezing
- wind
- weight loss
- dry skin
- spasms, aches and pains
- difficulty in beginning the flow of urine, difficulties in passing urine, involuntary passage of urine
- fever
- an increase in accidental injuries (e.g. falls)
- withdrawal symptoms such as agitation, anxiousness, sweating or shaking upon stopping using {[Nationally completed name]}

If you need to have blood tests remind your doctor that you are using {[Nationally completed name]}. This is important because {[Nationally completed name]} 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
- flushing of the skin
- difficulty in swallowing, ileus
- 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
- dehydration

Very rare (may affect up to 1 in 10,000 people)
- muscle twitching
- mood swings
- ear pain
- blisters
- drug dependence

Frequency 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.
- an increased sensitivity to pain
- colicky abdominal pain or discomfort
- feeling detached from oneself
- Withdrawal symptoms in babies born to mothers who have been given {[Nationally completed name]} in pregnancy may include high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties, sweating and not putting on weight.
- a need to take increasingly higher doses of this medicine to obtain the same level of pain relief (tolerance)
- dermatitis contact (skin rash with inflammation which may include burning sensation), 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 {[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 on the sachet after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.
Do not use the transdermal patch if you notice that the sachet seal is already broken.

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

Do not throw away any medicine 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.

{[Nationally completed name] 25 microgram/hour transdermal patch}:
Each transdermal patch contains 25 mg of buprenorphine per 31.25 cm^2, releasing 25 micrograms of buprenorphine per hour.
{[Nationally completed name] 30 microgram/hour transdermal patch}:
Each transdermal patch contains 30 mg of buprenorphine per 37.5 cm^2, releasing 30 micrograms of buprenorphine per hour.
{[Nationally completed name] 40 microgram/hour transdermal patch}:
Each transdermal patch contains 40 mg of buprenorphine per 50 cm^2, releasing 40 micrograms of buprenorphine per hour.

- The other ingredients are:
  Release liner (to be removed before applying the patch): poly(ethylene terephthalate) foil, siliconized
  Adhesive matrix (containing buprenorphine): levulinic acid, oleyl oleate, povidone K 90, poly[acrylic acid-co-butylacrylate-co-(2-ethylhexyl)acrylate-co-vinylacetate] (5:15:75:5)
  Separating film (between the adhesive matrices with and without buprenorphine: poly(ethylene terephthalate) foil
  Cover patch: acrylate adhesive, polyurethane backing foil, printing ink

What {[Nationally completed name]} looks like and contents of the pack
{[Nationally completed name]} is a pale yellowish-brown, rectangular transdermal patch with rounded edges, containing the following imprint:
'Buprenorphinum 25 µg/h'
'Buprenorphinum 30 µg/h'
'Buprenorphinum 40 µg/h'

Each transdermal patch is individually packed in a child resistant sachet.

Carton containing 4, 8 or 12 transdermal patches.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
Sandoz B.V.
Veluwezoom 22
1327 AH Almere
Nederland

Fabrikant:
Hexal AG
Industriestrasse 25
83607 Holzkrichen
Duitsland

In het register ingeschreven onder:
Buprenorfine Sandoz 25 microgram/uur 7 dagen, pleister voor transdermaal gebruik: RVG 128363
Buprenorfine Sandoz 30 microgram/uur 7 dagen, pleister voor transdermaal gebruik: RVG 128364
Buprenorfine Sandoz 40 microgram/uur 7 dagen, pleister voor transdermaal gebruik: RVG 128366

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Duitsland	Bupre-HEXAL 7 Tage 25 Mikrogramm/Stunde transdermales Pflaster
	Bupre-HEXAL 7 Tage 30 Mikrogramm/Stunde transdermales Pflaster
	Bupre-HEXAL 7 Tage 40 Mikrogramm/Stunde transdermales Pflaster
Finland	Buprenorphine Sandoz 30 mikrog/tunti depotlaastari
	Buprenorphine Sandoz 40 mikrog/tunti depotlaastari
Nederland	Buprenorfine Sandoz 25 microgram/uur 7 dagen, pleister voor transdermaal gebruik
	Buprenorfine Sandoz 30 microgram/uur 7 dagen, pleister voor transdermaal gebruik
	Buprenorfine Sandoz 40 microgram/uur 7 dagen, pleister voor transdermaal gebruik
Noorwegen	Bugnanto
Zweden	Buprenorphine Sandoz 30 mikrogram/timme depotplåster
	Buprenorphine Sandoz 40 mikrogram/timme depotplåster

Deze bijsluiter is voor het laatst goedgekeurd in juni 2022.