Package leaflet: Information for the patient

Bunov 15 microgram/hour transdermal patch
Bunov 30 microgram/hour transdermal patch
Bunov 40 microgram/hour transdermal patch

buprenorphine

This medicine contains buprenorphine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

- **These patches contain a strong pain killer**
- **Ensure that old patches are removed before applying a new one**
- **Patches must not be cut**
- **Do not expose the patches to a heat source (such as a hot water bottle)**
- **Do not soak in a hot bath or take a hot shower whilst wearing a patch**
- **If you develop a fever tell your doctor immediately**
- **Follow the dosage instructions carefully and only change your patch on the same day and at the same time 7 days later**
- **If your breathing becomes shallow and weak take the patch off and seek medical help**

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 Bunov is and what it is used for
2. What you need to know before you use Bunov
3. How to use Bunov
4. Possible side effects
5. How to store Bunov
6. Contents of the pack and other information

1. What Bunov is and what it is used for

This medicine has been prescribed for you to relieve moderate, long-lasting pain that requires the use of a strong painkiller. It contains buprenorphine which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Bunov should not be used to relieve acute pain.

2. What you need to know before you use Bunov

Do not use Bunov:
- 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.
- if you have pain which lasts only for a short period or pain after having an operation because of the increased risk of dependence and developing serious breathing problems.

If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital if you are currently treated with Bunov transdermal patch to discuss your pain management.
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Bunov must not be used to treat symptoms associated with drug withdrawal.

Warnings and precautions
Talk to your prescriber before taking this medicine if you:
• are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.

• have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

• feel you need to use more Bunov to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.
Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.
Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.
Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Talk to your doctor or pharmacist before using Bunov:
- if you are treated with antidepressants.
  The use of these medicines together with Bunov can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and Bunov”);
- if you suffer from seizures, fits or convulsions;
- if you suffer from a breathing related sleep 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 or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”);
- if you are a smoker;
- if 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 have a high temperature, as this may lead to larger quantities of the active ingredient being absorbed into the blood than normal.
- if you suffer from constipation.

Sleep-related breathing disorders
Bunov 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.

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 Bunov 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 Bunov 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 patches.

Similar to other opioids, Bunov 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.

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

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

- Anti-depressants such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with Bunov 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.
- Bunov must not be used together with a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, 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 Bunov may be reduced.
- Bunov 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 Bunov 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 Bunov 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.

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

Pregnancy, breast-feeding and fertility
Do not use Bunov patches if you are pregnant or think you may be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.
If you use Bunov patches during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.
Do not use Bunov patches while you are breastfeeding as buprenorphine passes into breast milk and will affect your baby.

You should not use Bunov 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
Bunov 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.
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Bunov can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

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

3. How to use Bunov

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

Different strengths of Bunov are available. Your doctor will decide which strength of Bunov 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 Bunov is too weak or too strong, talk to your doctor or pharmacist.

Your prescriber should have discussed with you how long the course of patches will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Adults and elderly patients
Unless your doctor has told you differently, attach one Bunov 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 Bunov. 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 Bunov may be affected and your doctor will therefore check on you more closely.

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

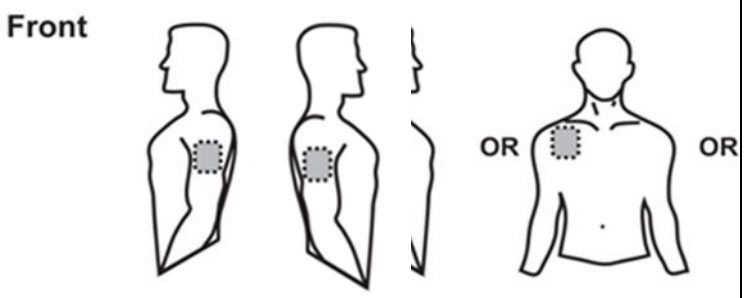
Method of administration
Bunov transdermal patch is for transdermal use.
Bunov act through the skin. After application, buprenorphine passes through the skin into the blood.

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



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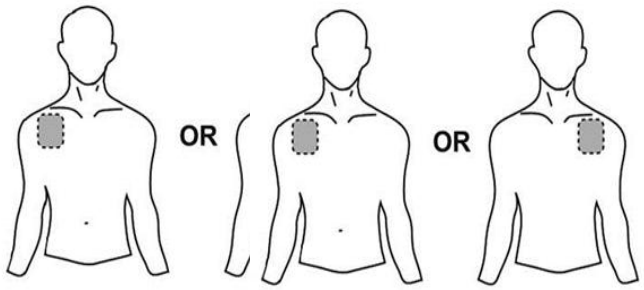

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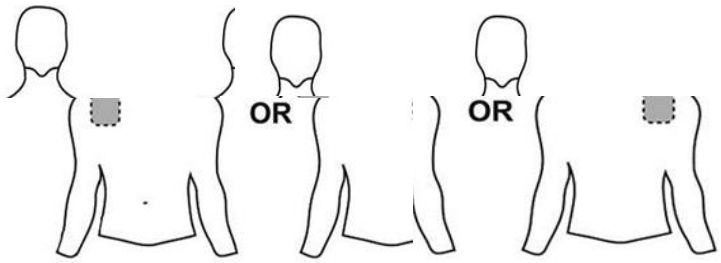

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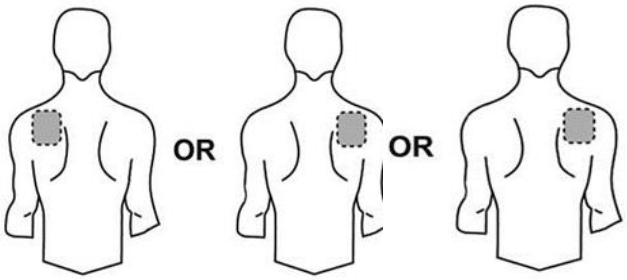


- The Bunov patch should be appli
  suitable hair free sites are availab
  shave them off.

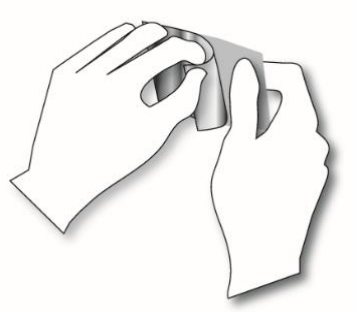
- Avoid skin which is red, irritated or has any other blemishes, for instance large scars.

- 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.

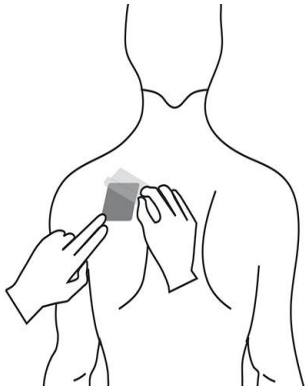
Applying the transdermal patch

- 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 Bunov (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 Bunov. Do not stop treatment without consulting a doctor, because your pain may return and you may feel unwell (see also "If you stop using Bunov" below).

If you use more Bunov 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 Bunov
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 Bunov
Do not suddenly stop using this medicine. If you want to stop using this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

If you stop using Bunov 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 Bunov 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 Bunov 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 Bunov 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.

Drug withdrawal
When you stop using Bunov patches you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst using Bunov patches, it could be a sign that you have become addicted.
• You need to use the patches for longer than advised by your prescriber;
• You feel you need to use more than the recommended dose;
• You are using the medicine for reasons other than prescribed;
• When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.
If you notice any of these signs it is important you talk to your prescriber

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 Bunov.
- 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 Bunov. This is important because Bunov 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.
- Dependence and addiction (see section 'How do I know if I am addicted?').

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Bunov

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.

15 microgram/h patches: Do not store above 25°C.

30 and 40 microgram/h patches: Do not store above 30°C.

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 Bunov patches contain

- The active substance is buprenorphine.
  Bunov 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).
  Bunov 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).
  Bunov 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 Bunov look like and contents of the pack

Transdermal patch
Bunov 15 microgram/hour: Each transdermal patch is beige coloured with rounded corners and is imprinted with “Buprenorphin” and “15 µg/h”
Bunov 30 microgram/hour: Each transdermal patch is beige coloured with rounded corners and is imprinted with “Buprenorphin” and “30 µg/h”
Bunov 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

Glenmark Pharmaceuticals Europe Limited
Laxmi House
2B Draycott Avenue
Kenton, Middlesex
HA3 0BU
United Kingdom

Manufacturer

Labtec GmbH
Heykenaukamp 10
21147 Hamburg
Germany

AdhexPharma
42/44 rue de Longvic

21300 Chenôve
France

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