Package leaflet: Information for the patient

BuTrans® 5 microgram/hour transdermal patches
BuTrans® 10 microgram/hour transdermal patches
BuTrans® 15 microgram/hour transdermal patches
BuTrans® 20 microgram/hour transdermal patches

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What *BuTrans* patches are and what they are used for

BuTrans patches 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.

BuTrans patches should not be used to relieve acute pain.

BuTrans patches act through the skin. After application, buprenorphine passes through the skin into the blood. Each patch lasts for seven days.

2. What you need to know before you use *BuTrans* patches

Do not use *BuTrans* patches:

- 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 tranylcypromine, 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.

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using ***BuTrans*** patches:

- if you are treated with antidepressants.
  The use of these medicines together with ***BuTrans*** patches can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and ***BuTrans*** patches");
- 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
BuTrans patches 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 ***BuTrans*** 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 ***BuTrans*** 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, ***BuTrans*** 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.

Children and adolescents

Do not give this medicine to children below 18 years.

Other medicines and *BuTrans* patches

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 ***BuTrans*** patches and may sometimes cause very serious reactions. Do not take any other medicines whilst taking ***BuTrans*** patches 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 ***BuTrans*** patches 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.
- ***BuTrans*** patches 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 ***BuTrans*** patches may be reduced.
- ***BuTrans*** patches 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 ***BuTrans*** patches 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 ***BuTrans*** patches 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.

Using *BuTrans* patches 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 ***BuTrans*** patches. Drinking alcohol whilst using ***BuTrans*** patches may also affect your reaction time.

Pregnancy, breast-feeding and fertility

You should not use ***BuTrans*** patches 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 taking this medicine.

Driving and using machines

BuTrans patches 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 ***BuTrans*** patches, or for 24 hours after removing the patch.

3. How to use *BuTrans* patches

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 ***BuTrans*** patches are available. Your doctor will decide which strength of ***BuTrans*** patch will suit you best.

When people first start using ***BuTrans***, 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 ***BuTrans*** patches to ensure that you are taking the correct dose and to manage any side effects.

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.**

Adults and elderly patients

Unless your doctor has told you differently, attach one ***BuTrans*** 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 the ***BuTrans*** patch. 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 under 18 years of age

BuTrans patches should not be used in patients below the age of 18 years.

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 ***BuTrans*** patch may be affected and your doctor will therefore check on you more closely.

Before applying the *BuTrans* patch

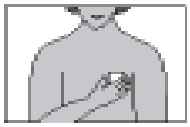
- Choose an area of non-irritated, intact skin on your upper arm, outer arm, upper chest, upper back or side of the chest. (See illustrations below). Ask for assistance if you cannot apply the patch yourself.

- The ***BuTrans*** 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 patch

Step 1: Each patch is sealed in a pouch. Just before use, cut the pouch along the dotted line with scissors. Be careful not to damage the transdermal patches with the scissors. Take out the patch. Do not use the patch if the pouch seal is broken.

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



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

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

Wearing the 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 ***BuTrans*** patches (see "Take special care" 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 patch" below).

Changing the patch

- Take the old patch off.
- Fold it in half with the sticky side inwards.
- Open and take out a new patch. Use the empty pouch to dispose of the old patch. Now discard the pouch safely.
- Even used patches contain some active ingredient 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 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 ***BuTrans*** patch. Do not stop treatment without consulting a doctor, because your pain may return and you may feel unwell (see also "If you stop using ***BuTrans*** patches" below).

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

If you use more *BuTrans* patches 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 apply the *BuTrans* patch

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 *BuTrans* patches

If you stop using ***BuTrans*** patches 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 ***BuTrans*** patches 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 ***BuTrans*** patch 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 ***BuTrans*** patches 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.

As with all strong painkillers, there is a risk that you may become addicted or reliant on ***BuTrans*** patches.

In patients treated with ***BuTrans*** patches, 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 heart beat.
- Cough, hiccups, wheezing.
- Wind.
- Weight loss.
- Dry skin.
- Spasms, aches and pains.
- Difficulty in beginning the flow of urine.
- Fever.
- An increase in accidental injuries (e.g. falls).
- Withdrawal symptoms such as agitation, anxiousness, sweating or shaking upon stopping using ***BuTrans*** patches.

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

Rare (may affect up to 1 in 1000 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.
- 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 ***BuTrans*** 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance at www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store *BuTrans* patches

Keep this medicine out of the sight and reach of children.

Do not use ***BuTrans*** patches after the expiry date which is stated on the carton and on the pouch. The expiry date refers to the last day of that month. After the expiry date, take any unused patches to a pharmacy.

Do not store ***BuTrans*** patches above 25°C.

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

Used patches must be folded over on themselves with the adhesive layer inwards, and discarded safely out of sight and reach of children.

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 *BuTrans* patches contain

The active ingredient is buprenorphine.

BuTrans 5 microgram/hour transdermal patch
Each transdermal patch contains 5 mg of buprenorphine in a patch size of 6.25 cm^2 and releases about 5 micrograms of buprenorphine per hour (over a period of 7 days).

BuTrans 10 microgram/hour transdermal patch
Each transdermal patch contains 10 mg of buprenorphine in a patch size of 12.5 cm^2 and releases about 10 micrograms of buprenorphine per hour (over a period of 7 days).

BuTrans 15 microgram/hour transdermal patch
Each transdermal patch contains 15 mg of buprenorphine in a patch size of 18.75 cm^2 and releases about 15 micrograms of buprenorphine per hour (over a period of 7 days).

BuTrans 20 microgram/hour transdermal patch
Each transdermal patch contains 20 mg of buprenorphine in a patch size of 25 cm^2 and releases about 20 micrograms of buprenorphine per hour (over a period of 7 days).

The other ingredients are:
- Polyacrylate (Durotak 387-2051 & 387-2054)
- Levulinic acid
- Oleyl oleate
- Povidone
- Polyethyleneterephthalate

What *BuTrans* patches look like and contents of the pack

Transdermal patch.

Four sizes are available.

5 microgram/hour: square, beige coloured patch with rounded corners marked ***BuTrans*** 5 µg/h

10 microgram/hour: rectangular, beige coloured patch with rounded corners marked ***BuTrans*** 10 µg/h

15 microgram/hour: rectangular, beige coloured patch with rounded corners marked ***BuTrans*** 15 µg/h

20 microgram/hour: square, beige coloured patch with rounded corners marked ***BuTrans*** 20 µg/h

BuTrans patches are available in cartons containing 2 or 4 child resistant pouches each containing a single patch.

Marketing Authorisation Holder

Mundipharma Pharmaceuticals Limited, United Drug House Magna Drive, Magna Business Park, Citwest Road, Dublin 24, Ireland.

Manufacturer

Mundipharma DC B.V., Leusderend 16, 3832 RC Leusden, The Netherlands.

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

Austria	Norspan®
Belgium	Norspan®
Czech Republic	Norspan®
Denmark	Norspan®
Estonia	Norspan®
Finland	Norspan®
Germany	Norspan®
Hungary	Norspan®
Iceland	Norspan®
Latvia	Norspan®
Lithuania	Norspan®
Luxembourg	Norspan®
Netherlands	BuTrans®
Norway	Norspan®
Poland	Norspan®
Portugal	Norspan®
Republic of Ireland	BuTrans®
Slovak Republic	Norspan®

Sweden Norspan®

This leaflet is also available in large print, Braille or as an audio CD. To request a copy, please call the RNIB Medicine Information line on: 0044 1733 37 5370
You will need to give details of the product name and reference number. These are as follows:
Product name: BuTrans patches
Reference number: 1688/2/1

This leaflet was last revised in February 2023