

## Package leaflet: Information for the patient

**Butec<sup>®</sup> 5 microgram/hour transdermal patches**

**Butec<sup>®</sup> 10 microgram/hour transdermal patches**

**Butec<sup>®</sup> 15 microgram/hour transdermal patches**

**Butec<sup>®</sup> 20 microgram/hour transdermal patches**

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, 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 effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

1. What **Butec** patches are and what they are used for
2. What you need to know before you use **Butec** patches
3. How to use **Butec** patches
4. Possible side effects
5. How to store **Butec** patches
6. Contents of the pack and other information

#### **1. What **Butec** patches are and what they are 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.

**Butec** patches should not be used to relieve acute pain.

**Butec** 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 **Butec** patches

### Do not use **Butec** patches if you:

- are allergic (hypersensitive) to buprenorphine or any of the other ingredients of this medicine (listed in section 6 of this leaflet);
- have a condition that is currently affecting or might affect your breathing. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- are addicted to drugs, or you are currently undergoing drug withdrawal. **Butec** patches must not be used to treat symptoms associated with drug withdrawal;
- are taking a type of medicine used to treat depression 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;
- suffer from myasthenia gravis (a condition in which the muscles become weak);
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping drinking alcohol.

### Warnings and precautions

Talk to your doctor, pharmacist or nurse before using **Butec** patches if you:

- have depression or other conditions that are treated with antidepressants. The use of these medicines together with **Butec** patches can lead to serotonin syndrome, a potentially life-threatening condition (see 'Other medicines and **Butec** patches');
- 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 **Butec** patches 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;
- are currently intoxicated from drinking alcohol;
- suffer from seizures, fits or convulsions. You may experience these more frequently whilst using this medicine;
- know you are suffering from a brain injury or tumour, or you have a head injury, severe headache or feel sick, as this may indicate that the pressure in your skull is increased. This is because the patches may make symptoms worse, or hide the extent of any head injury;
- have pale, cold, clammy skin, dizziness or light-headedness, fast, shallow breathing, or sweating. These are symptoms of shock;
- are feeling unusually light-headed or faint;
- have severe liver problems;
- have recently had an operation;
- have a high temperature, as this may lead to larger quantities of the active ingredient being absorbed into the blood than normal;
- have severely impaired lung function. Symptoms may include breathlessness and coughing;
- have a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea;
- are currently suffering from constipation.

Using 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.

### **Children and adolescents**

Do not give this medicine to children below 18 years.

### **Other medicines and *Butec* patches**

Some medicines may increase the side effects of *Butec* patches and may sometimes cause very serious reactions. Do not take any other medicines whilst using *Butec* patches without first talking to your doctor.

Using *Butec* patches at the same time as other medicines that slow down the central nervous system can cause slow or difficulty breathing (respiratory depression), severe sleepiness, loss of consciousness and death. These medicines include:

- other medicines used to treat pain known as opioids (such as codeine or morphine);
- medicines used to treat depression;
- medicines used to treat allergies (antihistamines);
- medicines used to make you feel sleepy (such as benzodiazepines);
- medicines used to treat anxiety;
- medicines used to treat psychiatric or mental disorders (such as phenothiazines);
- anaesthetics (such as halothane);
- medicines used to treat high blood pressure (such as clonidine);
- a type of medicine used to treat depression known as monoamine oxidase inhibitors (MAOIs), such as tranylcypromine, phenelzine and isocarboxazid. You should not use *Butec* patches if you are currently taking this type of medicine, or have taken this medicine in the last two weeks.

Because of this, your doctor will only prescribe *Butec* patches where there are no other treatment options, and only in small doses for short periods of time. If you or your friends, family or caregivers notice that you are having difficulty breathing or that you have become very sleepy or lost consciousness you (or they) should inform your doctor immediately.

Talk to your doctor before taking anti-depressants such as citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with *Butec* 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.

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 **Butec** patches may be reduced.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

#### **Pregnancy, breast-feeding and fertility**

Do not take **Butec** 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 **Butec** patches during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not use **Butec** patches while you are breastfeeding as buprenorphine passes into breast milk and will affect your baby.

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

#### **Driving and using machines**

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

- 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.

### **3. How to use *Butec* 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 **Butec** patches are available. Your doctor will decide which strength of **Butec** patch will suit you best.

When people first start using **Butec**, they often experience some nausea and vomiting (see section 4 of this leaflet). 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 **Butec** 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.**

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 **Butec** patch (as described in detail below) and change it once per week on the same day each week, 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 **Butec** 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**

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

#### **Before applying the **Butec** 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 **Butec** 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 (one week). 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 **Butec** patches (see section 2 'Warnings and precautions' 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 **Butec** 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 **Butec** patches' below).

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

### **If you use more *Butec* 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 **immediately**. 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 *Butec* 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 *Butec* patches**

Do not suddenly stop taking this medicine. If you want to stop taking 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 **Butec** patches too soon or you interrupt your treatment your pain may return.

The pain relieving effect of **Butec** 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, **Butec** patches can cause side effects, although not everybody gets them.

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. These may be signs of a serious allergic reaction.

The most serious side effect is a condition where you breathe more slowly or weakly than usual (respiratory depression) and can lead to severe sleepiness and loss of consciousness. This side effect may affect up to 1 in 1,000 people and is more likely to occur when taking certain other medicines (see section 2 'Other medicines and **Butec** patches'). Tell your doctor **immediately** if this happens to you. You may wish to ask your friends, family or caregivers to monitor you for these signs and symptoms.

#### Drug withdrawal

When you stop taking **Butec** 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 **Butec** 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 **Butec** 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 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 or puffiness of hands, ankles or feet.

#### **Uncommon** (may affect up to 1 in 100 people)

- allergic (hypersensitivity) reactions, including swelling of the face, lips or tongue, rash or itching;
- loss of control of your mood, changes to your sleeping habits, restlessness, agitation, a feeling of extreme happiness, hallucinations, reduced sexual drive, nightmares, aggression;
- feeling very drowsy, 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 (vertigo);
- high or low blood pressure, chest pain, fast or irregular heartbeat, flushing of the skin;
- cough, hiccups, wheezing;
- wind;
- weight loss;
- dry skin, a raised, itchy rash (hives), sometimes caused by an allergic reaction (contact dermatitis);
- muscle spasms, aches and pains;
- loss of bladder control, difficulty in beginning the flow of urine;
- inability to fully empty the bladder;
- fatigue, raised body temperature, sudden feeling of cold with a high temperature and sweating, water retention;
- an increase in accidental injuries (e.g. falls);
- withdrawal symptoms such as agitation, anxiousness, sweating or shaking upon stopping using **Butec** patches (see section 'Drug withdrawal').

If you need to have blood tests remind your doctor that you are using **Butec** patches. This is important because **Butec** 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 1,000 people)

- a severe allergic reaction (anaphylaxis), the symptoms of which include difficulty breathing, wheezing, severe swelling of the face, lips or tongue, rash or itching, and loss of consciousness (see above);
- angina (chest pain associated with heart disease);
- severe mental disorder causing loss of touch with reality (psychotic disorder);
- difficulties with balance;
- changes to your vision, swelling or puffiness of the eyelids or face, a reduction in size of the pupils in the eye;
- difficulty in breathing, worsening of asthma, very fast breathing (hyperventilation);
- a feeling of faintness, especially on standing up;
- difficulty in swallowing, a condition where the bowel doesn't work properly (ileus);
- 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)

- mood swings;
- involuntary muscle twitching;
- ear pain;
- blisters.

**Not known** (frequency cannot be estimated from the available data)

- 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;
- an increased sensitivity to pain;

- development of a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea;
- a need to take increasingly higher doses to obtain the same level of pain relief (drug tolerance);
- dependence and addiction (see section 'How do I know if I am addicted?').

Long term use of **Butec** patches during pregnancy may cause life-threatening withdrawal symptoms in the newborn. Symptoms to look for in the baby include irritability, hyperactivity and abnormal sleep pattern, high pitched cry, shaking, being sick, diarrhoea and not putting on weight.

### 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the 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 **Butec** patches

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

Do not use **Butec** 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 **Butec** 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 **Butec** patches contain

The active ingredient is buprenorphine.

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

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

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

Each **Butec** 20 microgram/hour transdermal patch contains 20 mg of buprenorphine in a patch size of 25 cm<sup>2</sup> 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 **Butec** patches look like and contents of the pack

**Butec** 5 microgram/hour transdermal patch is a square, beige coloured patch with rounded corners marked **Butec** 5 µg/h.

**Butec** 10 microgram/hour transdermal patch is a rectangular, beige coloured patch with rounded corners marked **Butec** 10 µg/h.

**Butec** 15 microgram/hour transdermal patch is a rectangular, beige coloured patch with rounded corners marked **Butec** 15 µg/h.

**Butec** 20 microgram/hour transdermal patch is a square, beige coloured patch with rounded corners marked **Butec** 20 µg/h.

**Butec** patches are available in cartons containing 4 child resistant pouches, each containing a single patch.

#### **Marketing Authorisation Holder**

Qdem Pharmaceuticals Limited, Cambridge Science Park, Milton Road, Cambridge CB4 0AB, UK.

#### **Manufacturer**

Bard Pharmaceuticals Limited, Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.

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 (free of charge) on: 0800 198 5000

You will need to give details of the product name and reference number. These are as follows:

Product name: **Butec** patches

Reference number: 40431/0024

#### **This leaflet was last revised in March 2021**

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