

Package leaflet: Information for the patient

Butec[®] 5 microgram/hour transdermal patches **Butec[®] 10 microgram/hour transdermal patches** **Butec[®] 15 microgram/hour transdermal patches** **Butec[®] 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 hot 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), or you have previously experienced an allergic skin reaction to buprenorphine patches;
 - 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:

- **Tolerance, dependence, and addiction**
This medicine contains buprenorphine which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of **Butec** can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

- The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to **Butec** if:
 - You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
 - You are a smoker.

- 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 notice any of the following signs whilst taking **Butec**, it could be a sign that you have become dependent or addicted.
 - You need to take the medicine for longer than advised by your doctor.
 - You need to take more than the recommended dose.

- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.
- You are using the medicine for reasons other than prescribed, for instance, "to stay calm" or "help you sleep".
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine.
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ("withdrawal effects").

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (see section 3. If you stop taking Butec).

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').

- You suffer from seizures, fits or convulsions. You may experience these more frequently whilst using this medicine;
- You 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.

- You have pale, cold, clammy skin, dizziness or light-headedness, fast, shallow breathing, or sweating. These are symptoms of shock.
- You are feeling unusually light-headed or faint;
- You have severe liver problems;
- You have recently had an operation;
- You have a high temperature, as this may lead to larger quantities of the active ingredient being absorbed into the blood than normal;
- You have severely impaired lung function. Symptoms may include breathlessness and coughing;
- You have a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea;
- You 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 heart beat (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. Sleep-related breathing disorders: **Butec** patches can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep-related hypoxaemia (low oxygen levels 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.

When using **Butec** patches you may experience mild to moderate skin reactions at the site where you have applied the patch. These include redness, swelling, itching, rash, small blisters and pain or burning sensation at the application site, which in some cases may be severe. In some cases a reaction may only begin after several months of treatment.

Applying the patches according to the instructions given in section 3 'How to use **Butec** patches' reduces the risk of experiencing these reactions.

Do not use **Butec** 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 **Butec** transdermal patch to discuss your pain management.

If you experience these symptoms you or your caregivers should remove the patch immediately and contact your doctor. Continued use of the patches after experiencing an allergic reaction can result in blistering of the skin, open wounds, bleeding, ulceration, infections, changes to the colour of the skin (hypo- and hyperpigmentation), and dry, thick, scaly, scar-like patches.

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 difficultly 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 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.

- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).
- Medicines to treat depression.
- Medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics).
- Muscle relaxants.
- Medicines to treat Parkinson's disease.

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, doxepin, 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.

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 the 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.

Before starting treatment and regularly during treatment, your doctor will discuss with you what

you may expect from using **Butec**, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, if you stop taking **Butec**).

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

NMA-9049-01

