

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

**®BuTrans**

#### **Buprenorphine Transdermal System**

Read this carefully before you start taking **BuTrans** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **BuTrans**.

#### **Serious Warnings and Precautions**

- Even if you take BuTrans as prescribed you are at risk for opioid addiction, abuse, and misuse. This can lead to overdose and death. To understand your risk of opioid addiction, abuse, and misuse, you should speak to your healthcare professional.
- Life-threatening breathing problems can happen while taking BuTrans, especially if not taken as directed. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.
- Never give anyone your BuTrans. They could die from taking it. If a person has not been prescribed BuTrans, touching the medicated side of a patch can cause a fatal overdose, especially children. Avoid accidental contact between the patch and other people, especially when holding, hugging, or caring for children.
- If you took BuTrans while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:
  - has changes in their breathing (such as weak, difficult or fast breathing);
  - is unusually difficult to comfort;
  - has tremors (shakiness);
  - has increased stools, sneezing, yawning, vomiting, or fever;get immediate medical help for your baby.
- Taking BuTrans with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

#### **What is BuTrans used for?**

BuTrans is used in adults (18 years of age and older) to manage long term pain, when:

- the pain is severe enough to require daily, around-the-clock pain medication; and
- the healthcare professional determines that other treatment options are not able to effectively manage your pain.

BuTrans is NOT used “as needed” to treat pain that you only have once in a while.

#### **How does BuTrans work?**

BuTrans is a painkiller belonging to the class of drugs known as opioids. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

### **What are the ingredients in BuTrans?**

Medicinal ingredient: Buprenorphine.

Non-medicinal ingredients: Aluminum acetylacetonate, levulinic acid, oleyl oleate, polyacrylate (dry solids), polyethylene terephthalate, and povidone.

### **BuTrans comes in the following dosage forms:**

Transdermal patches:

- **5 mg**, delivering 5 mcg of buprenorphine per hour for 7 days.
- **10 mg**, delivering 10 mcg of buprenorphine per hour for 7 days.
- **15 mg**, delivering 15 mcg of buprenorphine per hour for 7 days.
- **20 mg**, delivering 20 mcg of buprenorphine per hour for 7 days.

### **Do not use BuTrans if:**

- your healthcare professional did not prescribe it for you.
- you are allergic to buprenorphine or any of the other ingredients in BuTrans.
- you have previously used buprenorphine transdermal patches and had an allergic reaction (e.g., severe skin rash).
- you have mild or short term pain that can be controlled by the occasional use of pain medication including those available without a prescription.
- you have severe asthma, trouble breathing, or any other lung problems.
- you have a condition where the bowel does not work properly (ileus) or you have severe pain in your abdomen.
- you have a head injury.
- you have or have had a history with epilepsy (seizures).
- you suffer from alcoholism or alcohol withdrawal.
- you are being treated for narcotic withdrawal.
- you have a dependence on opioids.
- you are taking, or have taken within the past 2 weeks, a monoamine oxidase (MAO) inhibitor used to treat depression (e.g., phenelzine sulfate, tranylcypromine sulfate, moclobemide or selegiline).
- you are pregnant, breast-feeding, or in labour.
- you have a condition called myasthenia gravis.
- you have severe liver problems.
- are going to have, or recently had, a planned surgery or operation.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BuTrans. Talk about any health conditions or problems you may have, including if you:**

- have a history of illicit or prescription drug or alcohol abuse.
- have kidney, liver, or lung problems.
- have heart problems.
- have pancreas, bile duct, or gallbladder problems.
- have low blood pressure or low blood levels.
- have a sleep disorder which causes pauses in breathing or shallow breathing while sleeping (sleep apnea).
- have problems with your thyroid, adrenal, or prostate gland.
- suffer from chronic or severe constipation.
- have, or had in the past, problems with your mood (such as depression and anxiety), hallucinations, or other mental health problems.
- suffer from migraines.

- are planning on drinking alcohol. Drinking alcohol while taking BuTrans may cause dangerous side effects, including death. Do NOT drink alcohol while taking BuTrans.
- have a fever.
- are at risk of having seizures.
- are planning to become pregnant, or are able to become pregnant and are not using an effective birth control. Ask your healthcare professional if you are unsure.
- are planning to breast-feed.
- have difficulty urinating.
- are 65 years of age and older.
- have a condition that causes weakness or frailty.

**Other warnings you should know about:**

***Taking BuTrans can cause the following serious side effects:***

- ***Disorder of the adrenal gland:*** You may develop a disorder of the adrenal gland called adrenal insufficiency. This means that your adrenal gland is not making enough of certain hormones. You may experience symptoms such as:
  - nausea, vomiting;
  - feeling tired, weak, or dizzy;
  - decreased appetite.

You may be more likely to have problems with your adrenal gland if you have been taking opioids for longer than one month. Your healthcare professional may do tests, give you another medication, and slowly take you off BuTrans.

- ***Serotonin toxicity (also known as serotonin syndrome):*** BuTrans can cause serotonin toxicity, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop serotonin toxicity if you take BuTrans with certain anti-depressants or migraine medications.

Serotonin toxicity symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
  - muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
  - fast heartbeat, changes in blood pressure;
  - confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, coma.
- ***Sleep apnea:*** Opioids can cause a problem called sleep apnea (stopping breathing from time to time while sleeping). Tell your healthcare professional if you have a history of sleep apnea or if anyone notices that you stop breathing from time to time while sleeping.

See the **Serious side effects and what to do about them** table below for more information on these and other serious side effects.

***External heat sources***

Do not expose the patch area to sources of heat such as heating pads, electric blankets, hot water bottles, heated waterbeds, heat lamps, saunas, hot tubs, intensive sunbathing, etc. This may increase the drug's ability to go through the skin and result in an overdose. This may also occur if you develop a fever.

### ***Opioid dependence and addiction***

Like any opioid, BuTrans may cause mental and physical dependence. Buprenorphine also has the potential to cause addiction. There are important differences between physical dependence and addiction. Tolerance means that, over time, a higher dose may be needed to get the same level of pain relief. It is important that you talk to your healthcare professional if you have questions or concerns about addiction, physical dependence, or tolerance. Your healthcare professional should prescribe and administer BuTrans with the same degree of caution appropriate to the use of other oral opioid medications. It is not recommended to use these products for a long period of time.

### ***Pregnancy, nursing, labour and delivery***

Do not use BuTrans while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. BuTrans can then cause life-threatening breathing problems in your unborn baby or nursing infant. If you become pregnant while taking BuTrans, tell your healthcare professional right away.

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

Before you do tasks which may require special attention, you should wait until you know how you react to BuTrans. BuTrans can cause:

- drowsiness,
- dizziness, or
- light headedness.

This can usually occur after you take your first dose and when your dose is increased.

### ***Sexual function/reproduction***

Long term use of opioids may lead to a decrease in sex hormone levels. It may also lead to low libido (desire to have sex), erectile dysfunction or being infertile.

### ***Worsened pain***

Taking opioids for pain can sometimes have the unintended effect of making your pain feel worse (opioid-induced hyperalgesia) even though your opioid dose has been unchanged or increased. This can also include feeling pain in new places in your body, or feeling pain from something that would not normally hurt, for example, feeling pain from clothing touching your skin. Tell your healthcare professional if you notice a change like this in your pain while you are taking BuTrans.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### **Serious Drug Interactions**

Taking BuTrans with the following medicines can cause serious side effects, including breathing problems that can lead to death:

- alcohol, including prescription and non-prescription medications that contain alcohol. Do NOT drink alcohol while you are taking BuTrans. It can lead to drowsiness, unusually slow or weak breathing, serious side effects, or a fatal overdose.
- antiemetics, medicines used to prevent nausea or vomiting (e.g., aprepitant).
- antiepileptics, used to treat and prevent seizures (e.g., carbamazepine, phenytoin, and phenobarbital).
- antihistamines, medicines used to treat allergies.
- general anesthetics, medicines used during surgery (e.g., halothane).

- medicines used to help with sleep or that help reduce anxiety (e.g., benzodiazepines such as diazepam, lorazepam, alprazolam, flunitrazepam; tranquilizers; and hypnotics such as barbiturates).
- medicines used to treat high blood pressure (e.g., clonidine).
- monoamine oxidase (MAO) inhibitors, medicines used to treat depression. Do NOT take BuTrans with MAO inhibitors or if you have taken a MAO inhibitors in the last 14 days.
- other opioids analgesics, medicines used to treat pain (e.g., butorphanol, nalbuphine, and pentazocine).
- other sedative drugs which may enhance the drowsiness caused by BuTrans.

**The following may also interact with BuTrans:**

- antibiotics, medicines used to treat bacterial infections (e.g., troleandomycin, clarithromycin, erythromycin, and rifampin).
- anticoagulants, medicines used to prevent or treat blood clots (e.g., warfarin, coumadin).
- antifungals, medicines used to treat fungal infections (e.g., itraconazole, ketoconazole, and fluconazole).
- antiretrovirals, medicines used to treat HIV/AIDS (e.g., nelfinavir, ritonavir, amprenavir, and fosamprenavir).
- calcium channel blockers, medicines used to treat high blood pressure and chest pain (e.g., verapamil and diltiazem).
- medicines used to treat depression and mood disorders (e.g., Selective Serotonin Re-Uptake Inhibitors (SSRIs), Serotonin Norepinephrine Re-Uptake Inhibitors (SNRIs), nefazodone, phenothiazines, and St. John's Wort).
- medicines used to treat irregular heart rhythms (e.g., amiodarone).
- grapefruit juice.

**How to take BuTrans:**

- Take BuTrans exactly as directed by your healthcare professional.
- BuTrans is an adhesive, rectangular or square patch that is placed on your skin. The patch slowly releases buprenorphine over a period of 7 days.

**BuTrans should only be used on the skin.**

- always remove the old patch before applying a new one. This is important to avoid overdose.
- apply on clean, dry, intact, non-hairy area on your upper chest, upper back, or upper arm. If the area you choose has body hair, clip (do not shave) the hair close to the skin with scissors.
- if you need to clean the skin where the patch will be applied, use only clear water.

**To avoid unwanted and potentially dangerous side effects:**

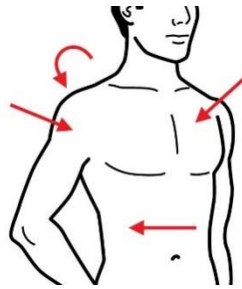
- Do **NOT** apply heat to the area before or after applying the patch.
- Do **NOT** chew, swallow, put it in your mouth, or use the patch in any way other than on the skin.
- Do **NOT** wear more than one patch at a time, unless your healthcare professional tells you to.
- Do **NOT** use the BuTrans patch if the seal is broken or the patch is cut, damaged or changed in any way.
- Do **NOT** apply your patch in front of children since they may copy your actions.

You can bathe, swim, or shower while wearing BuTrans. If the patch falls off, discard the patch properly. Apply a new patch at a different skin site. Make sure the new skin area is dry. Tell your healthcare professional that this has happened. Change this new patch after the usual 7 days.

**Where to Apply BuTrans:**

Select a dry, hairless or nearly hairless area, on your upper chest (left or right), upper back (left or right) side of chest (left or right) or upper outer arm (left or right) (see Figure A).

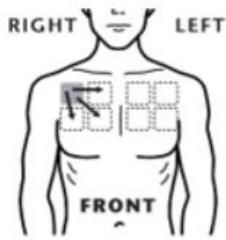
**Application Areas**



**Figure A**

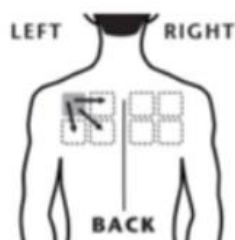
Within each of the application **AREAS** there is more than one possible **SITE** for applying the patch.

Possible application **SITES** in upper chest areas (left or right) (see Figure B), or the upper back areas (left or right) (see Figure C), or the right side of the chest and upper arm (see Figure D), or the left side of the chest and upper arm (see Figure E).



**Figure B**

OR



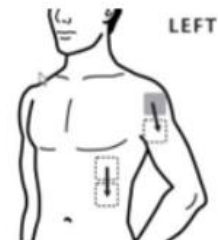
**Figure C**

OR



**Figure D**

OR



**Figure E**

Do not apply more than one patch at the same time unless prescribed by your healthcare professional.

If your healthcare professional tells you to use two patches make sure you apply **both** patches at the same time and at the same site right next to each other (see Figure F). Make sure you always:

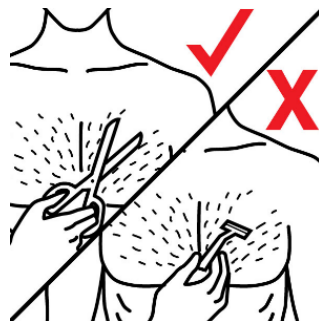
- apply **both** patches at the same time
- remove **both** patches at the same time



**Figure F**

**Do not** use more than a total **combined** dose from all patches of 20 mcg per hour.

If the area (site) you choose has body hair, **do not** shave the hair. Clip the hair close to the skin with scissors (see Figure G).



**Figure G**

Do not put the patch on skin that is excessively oily, burned, broken out, cut, irritated or damaged in any way. If you need to clean the skin where the patch will be applied, use only clear water. Soaps, oils, lotions, alcohol or other products may irritate the skin under the patch.

**How to Apply BuTrans:**

**Step 1-** Each patch is sealed in its own protective pouch. Do not remove the patch from the pouch until you are ready to use it. When you are ready, cut the pouch along the dotted line with scissors. Be careful not to damage the transdermal patches with the scissors (See Figure H).



**Figure H**

Take out the patch. Do not use the patch if the pouch seal is broken (See Figure I).



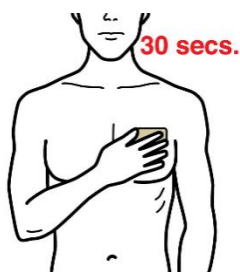
**Figure I**

**Step 2** - A protective liner covers the sticky side of the patch – the side that will be put on your skin. Remove the thin section of liner located at one side of the patch and apply the thin sticky side of the patch to a dry area of your upper chest, upper back, side of chest, or upper outer arm (see Figure J).



**Figure J**

**Step 3** - Remove the remainder of the liner and immediately press the patch firmly on your skin with the palm of your hands for about 30 seconds. Try not to touch the sticky side of the patch. Throw away the liner (see Figure K).



**Figure K**

Not all adhesive products stick to all patients. If an edge of the patch does not stick well, or loosens after application, tape the edges down with first aid tape. When applying the first aid tape, do not cover any printing on the BuTrans patch. In the event that the patch falls off, discard it and put a new one on at a different skin site. If two patches were applied at the same time and one falls off, remove the second patch from the body. Throw both of these patches away. Apply two **new** patches next to each other on a different skin site (see Disposal instructions below).

**Step 4** - Wash your hands, with water, when you have finished applying the patch.

**Step 5** - After wearing the patch for 7 days, or as directed by your healthcare professional, remove it (see **Disposal** instructions below). Then choose a different area (to apply a new patch and repeat steps 1 to 4 in order. The same area should not be re-used within 3 weeks. This will reduce the possibility of developing a rash. When returning to a previously used area after at least 3 weeks, a different skin site within the area should be used if possible.

Contact your healthcare professional if you have any questions about applying BuTrans.



**Safety and Handling:**

BuTrans is sealed to keep the drug adhesive layer from getting on your hands or body. If the drug adhesive layer accidentally touches the skin, wash the area with large amounts of water. Do not use soap, alcohol, or other solvents as these may increase the drug's ability to go through the skin.

Serious medical consequences, including death, can occur when patches are accidentally transferred to other people during skin-to-skin contact, for example while hugging, sharing a bed or moving a patient. If your patch dislodges and accidentally sticks to the skin of another person, take the patch off the other person immediately and call a healthcare professional. This is true for both fresh and used patches, as there is drug that remains in the patch after use.

**Usual dose:**

Dosage is individualized. Be sure to follow your healthcare professional's dosing interactions exactly. Do not increase or decrease your dose without consulting your healthcare professional. Taking higher doses can lead to more side effects and a greater chance of overdose.

Because the medicine in BuTrans is gradually released from the patch, and slowly absorbed through the skin, do not expect immediate relief after you apply your first patch. During this initial period, your healthcare professional may ask you to take additional pain medicine until you experience the full benefits of BuTrans.

If you continue to have pain, call your healthcare professional.

***Stopping your Medication:*** Please do not suddenly stop taking BuTrans as it may cause unwanted side effects.

Your healthcare professional will monitor and guide you on how to slowly stop taking BuTrans. You should do it slowly to avoid uncomfortable symptoms such as having:

- body aches;
- diarrhea;
- goosebumps;
- loss of appetite;
- nausea;
- feeling nervous or restless;
- runny nose;
- sneezing;
- tremors or shivering;
- stomach cramps;
- rapid heart rate (tachycardia);
- having trouble with sleeping;
- an unusual increase in sweating;
- heart palpitations;
- an unexplained fever;
- weakness;
- yawning.

By reducing or stopping your opioid treatment, your body will become less used to opioids. If you start treatment again, you will need to start at the lowest dose. You may overdose if you restart at the last dose you took before you slowly stopped taking BuTrans.

**Refilling Prescriptions for BuTrans:** A new written prescription is required from your healthcare professional each time you need more BuTrans. Therefore, it is important that you contact your healthcare professional before your current supply runs out.

Only obtain prescriptions for this medicine from the healthcare professional in charge of your treatment. Do not seek prescriptions from other healthcare professionals unless you switch to another healthcare professional for your pain management.

**Overdose:**

Signs of overdose may include:

- confusion;
- dizziness;
- extreme drowsiness;
- toxic leukoencephalopathy (a brain disorder affecting the brain's white matter);
- unusually slow or weak breathing.

If you, or a person you are caring for, are having the above signs of overdose, check all areas of their skin and remove any patches. There may be more than one patch, if a previous patch was not removed. Get immediate emergency medical help.

If you think you, or a person you are caring for, have taken too much BuTrans, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If a patch is left on for more than 7 days, remove the patch and apply a new patch following the instructions given. See the **How to use BuTrans** section above for more information.

**What are possible side effects from using BuTrans?**

These are not all the possible side effects you may have when taking BuTrans. If you experience any side effects not listed here, tell your healthcare professional.

**Side effects may include:**

- application site reactions (e.g., itching, redness, and/or rash);
- anorexia;
- constipation. Talk with your healthcare professional about ways to prevent constipation when you start using BuTrans;
- dizziness;
- drowsiness, insomnia;
- dry mouth;
- headache;
- lack of muscle strength;
- nausea, vomiting;
- sweating;
- low sex drive, impotence (erectile dysfunction), infertility;

These side effects may be more pronounced if you have a fever. If you develop a fever while using the patch, contact your healthcare professional.

Be aware that side effects may last for more than 24 hours after removal of the patch. This is because removing the patch does not completely remove the source of drug, as drug is deposited under the skin and so there will continue to be some drug released into the bloodstream for a few days after the patch removal.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>RARE</b>			
<b>Allergic reaction:</b> itchy, red, painful, and irritated or swollen skin (rash), outbreak of pale red bumps or welts on the skin that appear suddenly (hives), swelling of the face, lips, tongue or throat, difficulty swallowing (dysphagia), or difficulty breathing (dyspnea).			✓
<b>Bowel blockage</b> (impaction): abdominal pain, severe constipation, or nausea.			✓
<b>Fast, slow or irregular heartbeat:</b> heart palpitations.		✓	
<b>Hypotension</b> (low blood pressure): dizziness, fainting, or light-headedness.	✓		
<b>Overdose:</b> hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, dizziness, floppy muscles/low muscle tone (hypotonia), or cold and clammy skin.			✓
<b>Respiratory depression:</b> slow, shallow, or weak breathing.			✓
<b>Serotonin toxicity (also known as serotonin syndrome):</b> a reaction which may cause feelings of agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (>38°C), or rigid muscles.			✓
<b>Withdrawal:</b> nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, or sweating.		✓	
<b>UNKNOWN FREQUENCY</b>			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Disorder of the adrenal gland:</b> nausea, vomiting, anorexia, fatigue, weakness, dizziness, or low blood pressure.			✓
<b>Sleep apnea:</b> stop breathing for short periods during your normal nightly sleep.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

- Store BuTrans between 15°C and 30°C. Do not freeze. Keep BuTrans in its protective pouch until you are ready to use it.
- The inside of car can reach temperature much higher than 30°C on a sunny day. Do not carry the pouch in your pocket as it may reach body temperature (36°C).
- Keep unused or expired BuTrans in a secure place to prevent theft, misuse or accidental exposure.
- Keep BuTrans under lock, out of sight and reach of children and pets.
- Never take medicine in front of small children as they will want to copy you. Accidental ingestion by a child is dangerous and may result in death. If a child accidentally takes BuTrans, get emergency help right away.

**Disposal:** To prevent accidental exposure, and to reduce the chance of accidental contact with the medication, it is important to properly dispose of any used or excess BuTrans patches as soon as they are no longer needed. Upon removal of the used patch, fold the patch in half so the sticky side sticks to itself. Unused patches should be removed from their pouch and also folded in half so the sticky side sticks to itself. If the drug adhesive layer accidentally contacts the skin, the area should be washed with clear water.

Wash your hands, with water only, after removing the patch. **BuTrans should never be thrown into household trash, where children and pets may find it.** It should be returned to a pharmacy for proper disposal.

**If you want more information about BuTrans:**

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.purdue.ca>, or by calling 1-800-387-4501.

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