

SUMMARY OF INFORMATION ABOUT BUTRANS

The information below does not take the place of talking with your healthcare provider about your medical condition or your treatment.

WARNING: ADDICTION, ABUSE, and MISUSE; LIFE-THREATENING BREATHING PROBLEMS; ACCIDENTAL EXPOSURE; and WITHDRAWAL SYNDROME IN NEWBORNS; and RISKS FROM USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse

BUTRANS® (buprenorphine) is a long-acting (extended-release) opioid pain medicine that can put you and other users at risk for overdose and death. Even if you use your dose correctly as prescribed, you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Life-Threatening Breathing Problems

When you first start using BUTRANS, or when your dose is increased, serious or life-threatening breathing problems that can lead to death may occur, and may occur even at recommended doses during the normal course of therapy. Do not chew, swallow, snort, or inject buprenorphine from the patch because this can lead to overdose and death.

Accidental Exposure

Accidental exposure, especially in children, may result in breathing problems, overdose, or death.

Withdrawal Syndrome in Newborns

Prolonged use of BUTRANS when you are pregnant can cause withdrawal symptoms in your newborn baby that may be life-threatening if not recognized and treated.

Use with Benzodiazepines or Other CNS Depressants

Use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, can result in severe drowsiness, breathing problems, coma and death.

What is Butrans?

- Butrans® (buprenorphine) Transdermal System is a strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain that is severe enough to require daily, around-the-clock, long-term treatment with an opioid, when other pain treatments such as nonopioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them
- Butrans is a long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you use Butrans correctly as prescribed, you are at risk for opioid addiction, abuse, and misuse that can lead to death
- Butrans is only used to treat pain that continues around-the-clock (pain that is constant)
- Butrans is for use on intact and non-irritated skin only. Each Butrans patch should be worn continuously for 7 days

Who should not use Butrans?

- People who have any of these medical conditions should NOT use Butrans:
 - Severe asthma, trouble breathing, or other lung problems
 - A bowel blockage or narrowing of the stomach or intestines
 - Allergies to buprenorphine (the opioid in Butrans)
- Butrans should not be used in patients younger than 18 years of age

What warnings should I know before using Butrans?

- Use of Butrans, even when used as recommended, can result in addiction, abuse, and misuse, which could lead to overdose and death
- Using Butrans in any way other than how it is prescribed, including chewing or swallowing it or putting it in the mouth, may lead to choking, overdose, or death
- Using Butrans without a prescription is against the law and may lead to criminal charges. Opioid medications such as Butrans are sought by people who abuse drugs or have problems with addiction. Store Butrans in a safe place to help prevent abuse
- Never give anyone else your Butrans. They could die from using it. Store Butrans away from children and in a safe place to help prevent abuse or theft. Selling or giving away Butrans is against the law
- The risk of serious or life-threatening breathing problems that could lead to death can occur even at recommended doses. The risk is greatest when you first start using Butrans or when your dose is increased. Patients who have lung disease or are elderly, frail, or in poor general health are at increased risk, especially if Butrans is given with other drugs that cause breathing problems
- If you experience breathing problems caused by Butrans and are not treated right away, you could stop breathing and die. Get emergency help right away if you have trouble breathing or use too much Butrans (overdose)
- Accidental exposure, especially in a child, may result in breathing problems, overdose, or death
- Be sure to store Butrans safely and to dispose of unused patches when Butrans is no longer needed; use the Patch-Disposal Unit, or fold the patch in half and flush it down the toilet (see the detailed Instructions for Use provided with the Butrans patch)
- Using Butrans with other opioid medicines, benzodiazepines, alcohol or other central nervous system depressants, such as sleeping pills, medicines for anxiety, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, or street drugs may cause severe drowsiness, decreased awareness, low blood pressure, breathing problems, coma, and death. Do not use these types of medicines together unless you are directed to do so by your healthcare provider
- Butrans could cause adrenal insufficiency, a potentially life-threatening condition which may cause symptoms of nausea, vomiting, anorexia, fatigue, weakness, dizziness and low blood pressure. Seek medical attention if you experience these symptoms
- Butrans should be avoided if you have a history of Long QT Syndrome or an immediate family member with this condition, or if you are taking certain medicines for heart rhythm abnormalities
- Butrans may cause symptoms of low blood pressure, such as dizziness, lightheadedness, or fainting. If you experience these symptoms, you should sit or lie down and be careful when you get up from a sitting or lying position
- Butrans may complicate head injuries. Butrans should not be used by those with disturbances in consciousness or coma
- In rare cases, burns or blisters may develop on the skin where Butrans has been applied. This can happen soon after you start using Butrans, or after you have already been using it for a while. If your skin develops burns or blisters where you've applied Butrans, contact your healthcare provider right away; he or she may instruct you to discontinue Butrans
- Some people are, or may become, sensitive or allergic to buprenorphine (the opioid in Butrans) while using Butrans. This may lead to itching, swelling, and rashes or hives on the skin; in some cases, reactions including swelling of the lips, tongue, roof of mouth, throat, or windpipe may occur, making it difficult to swallow or breathe

- Do NOT expose Butrans or the skin near where Butrans is applied to hot water or prolonged direct sunlight; avoid sunbathing, taking hot baths, hot tubs, saunas, heating pads, electric blankets, heated waterbeds, and heat or tanning lamps. These activities can increase the amount of medicine your Butrans delivers and cause an overdose that can lead to death
- Butrans may increase the frequency of seizures in patients who experience seizures and may increase the risk of seizures. Tell your healthcare provider if you have a history of seizures
- Do NOT drive or operate heavy machinery until you know how Butrans affects you. Butrans can make you sleepy, dizzy, or lightheaded, and may reduce your mental and physical ability to perform these activities safely

What should I tell my healthcare provider?

- Tell your healthcare provider if you are pregnant or planning to become pregnant. Prolonged use of Butrans while you are pregnant can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated. Butrans can cause fetal harm. Chronic use of opioids may cause reduced fertility
- Tell your healthcare provider if you are breastfeeding. Breastfeeding is not recommended during treatment with Butrans. It may harm your baby
- The amount of buprenorphine a baby might receive from breastfeeding depends on the dose of Butrans the mother is using, how much milk the baby consumes, and how the mother's body processes Butrans. Breast-fed babies may experience withdrawal symptoms when their mothers stop using Butrans
- Tell your healthcare provider about any prescription or over-the-counter medicines, vitamins, or herbal supplements you are taking. Using Butrans with certain other medicines can cause serious side effects
- Tell your healthcare provider if you have or have had a head injury or seizure; problems breathing or urinating; an intestinal blockage; liver, kidney, thyroid, pancreas, or gallbladder problems; heart rhythm abnormalities (Long QT Syndrome); abuse of street or prescription drugs, alcohol addiction, or mental health problems
- Tell your healthcare provider if you develop a fever

What if I use too much Butrans?

- Get emergency help right away if you use too much Butrans. Using too much Butrans can result in an overdose, and can cause serious or life-threatening breathing problems that can lead to death

What side effects might I have while taking Butrans?

- The most common side effects reported by patients treated with Butrans in the clinical trials were nausea, headache, application site itch, dizziness, constipation, sleepiness, vomiting, application site redness, dry mouth, and application site rash. Call your healthcare provider if you have any of these symptoms and they are severe
- The most common serious side effects occurring during clinical trials with Butrans included chest pain, abdominal pain, vomiting, dehydration, and increased blood pressure
- Get emergency medical help if you have trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion
- These are not all the possible side effects of Butrans. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. For more information, go to dailymed.nlm.nih.gov

What other medicines might interact with Butrans?

- Using Butrans with other opioid medicines, benzodiazepines, alcohol or other central nervous system depressants, such as sleeping pills, medicines for anxiety, tranquilizers, muscle relaxants, general anesthetics, antipsychotics or street drugs may cause severe drowsiness, decreased awareness, low blood pressure, breathing problems, coma, and death. Do not use these types of medicines together unless you are directed to do so by your healthcare provider
- It is extremely dangerous to self-administer benzodiazepines while using Butrans. Do not use these types of drugs unless you are told to do so by your healthcare provider
- When using Butrans, do not drink alcohol or use prescription or over-the-counter medicines containing alcohol. Using products containing alcohol during treatment with Butrans may cause you to overdose and die
- Some medicines (cytochrome P450 3A4 inhibitors including antibiotics such as erythromycin, anti-fungal medicines such as ketoconazole, and medicines for HIV such as ritonavir) can increase the amount of buprenorphine (the opioid in Butrans) in your blood if you take them while using Butrans. This may lead to breathing problems and extreme drowsiness. Tell your healthcare provider if you are taking these types of medicines before using Butrans
- If you stop taking certain other medicines (cytochrome P450 3A4 inducers, including carbamazepine, phenytoin, and rifampin) while you are using Butrans, this may increase the amount of buprenorphine (the opioid in Butrans) in your blood and may cause adverse effects and serious breathing problems. Tell your healthcare provider before you stop taking any other medicines you have been taking regularly while using Butrans
- Opioids could cause a rare but potentially life-threatening condition resulting from use with serotonergic drugs (e.g. selective serotonin reuptake inhibitors [SSRIs]), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), triptans, 5-HT₃ receptor antagonists, drugs that affect the serotonin neurotransmitter system (e.g., mirtazapine, trazodone, tramadol), monoamine oxidase (MAO) inhibitors (those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue). Tell your healthcare provider if you are taking or plan to take serotonergic drugs
- Avoid using Butrans while using any drugs that inhibit monoamine oxidase including phenelzine, tranylcypromine, linezolid
- Avoid using Butrans with mixed agonist/antagonist opioid analgesics including butorphanol, nalbuphine and pentazocine
- The use of buprenorphine (the opioid in Butrans) with muscle relaxants may cause increased breathing problems
- Opioids can reduce the efficacy of diuretics
- The use of buprenorphine (the opioid in Butrans) with anticholinergic drugs may cause urinary retention and/or severe constipation which may lead to bowel blockage

The risk information provided here is not comprehensive. To learn more, talk with your healthcare provider or pharmacist. The FDA-approved product labeling can be found at Purduepharma.com/ButransPI or 1-888-726-7535.

Distributed by: Purdue Pharma L.P., Stamford, CT 06901-3431
www.purduepharma.com or call 1-888-726-7535

Butrans®
(buprenorphine) Transdermal System
5, 7.5, 10, 15, and 20 mcg/hour