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Buprenorphine Transdermal Patch

pronounced as (byoo pre nor' feen)

IMPORTANT WARNING:

Buprenorphine patches can be habit-forming. Do not apply more patches, apply the patches more often, or use the patches in a different way than prescribed by your doctor. Tell your doctor if you or anyone in your family drinks or has ever drunk large amounts of alcohol; uses or has overused prescription medications; uses or has ever used street drugs; or has or has ever had depression or another mental illness. There is a greater risk that you will overuse buprenorphine patches if you have or have ever had any of these conditions.

Buprenorphine patches may cause serious or life-threatening breathing problems, especially during the first 72 hours of your treatment and any time that your dose is increased. Your doctor will monitor you carefully during your treatment. Tell your doctor if you have or have ever had breathing difficulties, asthma, chronic obstructive pulmonary disease (COPD; a group of diseases that affect the lungs and airways), or other lung disease. Your doctor may tell you not to use buprenorphine patches. Tell your doctor and pharmacist if you are taking atazanavir (Reyataz); benzodiazepines such as such as alprazolam (Xanax), chlordiazepoxide (Librium), clonazepam (Klonopin), diazepam (Diastat, Valium), estazolam, flurazepam, lorazepam (Ativan), oxazepam, temazepam (Restoril), triazolam (Halcion); medications for mental illness and nausea; other medications for pain; muscle relaxants; sedatives; sleeping pills; and tranquilizers. If you have any of the following symptoms, call your doctor immediately: difficulty breathing; extreme drowsiness with slow breathing; heartbeat that is slower than normal; cold clammy skin; difficulty thinking, talking, or walking normally; confusion; extreme tiredness; fainting; or loss of consciousness.

Do not allow anyone else to use your medication. Accidental exposure, especially in children, may result in serious harm or death. Store buprenorphine patches in a safe place so that no one else can use them accidentally or on purpose. Be especially careful to keep

buprenorphine patches out of the reach of children. Keep track of how many patches are left so you will know if any are missing.

Tell your doctor if you are pregnant or plan to become pregnant. If you use buprenorphine patches regularly during your pregnancy, your baby may experience life-threatening withdrawal symptoms after birth. Tell your baby's doctor right away if your baby experiences any of the following symptoms: irritability, hyperactivity, abnormal sleep, high-pitched cry, uncontrollable shaking of a part of the body, vomiting, diarrhea, or failure to gain weight.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with buprenorphine patches and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of using this medication.

Why is this medication prescribed?

Buprenorphine patches are used to relieve severe pain in people who are expected to need pain medication around the clock for a long time and who cannot be treated with other medications. It is in a class of medications called opiate (narcotic) analgesics. It works by changing the way the brain and nervous system respond to pain.

How should this medicine be used?

Transdermal buprenorphine comes as a patch to apply to the skin. The patch is usually applied to the skin once every 7 days. Change your patch at about the same time of day every time you change it. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Apply buprenorphine patches exactly as directed.

Your doctor may start you on a low dose buprenorphine patch and gradually increase your dose, not more often than once every 3 days. If this increase involves the use of two patches, remove your current patch and at the same time, place the two new patches next to each other at a new site. If your doctor tells you to use two patches, you should always change and apply them at the same time. Your doctor may decrease your dose if you experience side effects. Contact your doctor if the dose you are taking does not control your pain. Talk to your

doctor about how you are feeling during your treatment with buprenorphine patches.

Buprenorphine skin patches are only for use on the skin. Do not place patches in your mouth or chew or swallow the patches.

Do not stop using buprenorphine patches without talking to your doctor. Your doctor will probably decrease your dose gradually. If you suddenly stop using buprenorphine patches you may have symptoms of withdrawal. Call your doctor if you experience any of these symptoms of withdrawal: restlessness, teary eyes, runny nose, yawning, sweating, chills, hair standing on end, muscle aches, large pupils (black circles in the center of the eyes), irritability, diarrhea, nausea, vomiting, anxiety, pain in the joints, weakness, fast heartbeat, or rapid breathing.

Do not use a buprenorphine patch that is cut, damaged, or changed in any way. If you use cut or damaged patches, you may receive most or all of the medication at once, instead of slowly over 7 days. This may cause serious problems, including overdose and death.

If your buprenorphine patch is exposed to extreme heat, it may release too much medication into your body at once. This can cause serious or life-threatening symptoms. Do not expose your patch or the skin around it to direct heat such as heating pads, electric blankets, heat lamps, saunas, hot tubs, and heated water beds. Do not take long, hot baths or sunbathe while you are wearing the patch.

You may bathe or shower while you are wearing a buprenorphine patch. If the patch falls off during these activities, dispose of it properly. Then dry your skin completely and apply a new patch. Leave the new patch in place for 7 days after you apply it.

You can apply a buprenorphine patch to your upper outer arms, upper chest, upper back, or the side of your chest. Choose an area of skin that is flat and hairless. Do not apply the patch to parts of the body that irritated, broken, cut, damaged, or changed in any way. If there is hair on the skin, use scissors to clip the hair as close to the skin as possible. Do not shave the area. Wait at least 3 weeks before applying a new patch to same site.

To apply the patch, follow these steps:

1. Clean the area where you plan to apply the patch with clear water and pat completely dry. Do not use any soaps, lotions, alcohols, or oils.
2. Use scissors to cut open the pouch containing the buprenorphine patch along the dotted line. Remove the patch from the pouch and peel off the protective liner from the back of the patch. Try not to touch the sticky side of the patch.
3. Immediately press the sticky side of the patch onto the chosen area of skin with the palm of your hand.
4. Press the patch firmly for at least 15 seconds. Be sure that the patch sticks well to your

skin, especially around the edges. Do not rub the patch.

5. If the patch does not stick well or comes loose after it is applied, tape only the edges to your skin with first aid tape. If the patch still does not stick well, you may cover it with Bioclusive or Tegaderm brand see-through dressings. Do not cover the patch with any other type of bandages or tape. Talk to your doctor or pharmacist if your patch continues to have problems sticking to your skin.
6. If a patch falls off before it is time to remove it, dispose of the patch properly and apply a new patch at a different area of skin. Leave the new patch in place for 7 days.
7. When you are finished applying the patch, wash your hands with only clear water right away.
8. Write down the date and time that the patch is applied.
9. When it is time to change your patch, peel off the old patch and apply a new patch to a different skin area.
10. After you remove your patch, fold it in half with the sticky sides together and flush it down a toilet. You may also use a Patch Disposal Unit provided to you by the manufacturer to safely dispose of the used patch in the trash. Used patches may still contain some medication and may be dangerous to children, pets, or adults who have not been prescribed buprenorphine patches.

Other uses for this medicine

Buprenorphine should not be used to treat mild or moderate pain, short-term pain, or pain that can be controlled by medication that is taken as needed.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using buprenorphine patch,

- tell your doctor and pharmacist if you are allergic to buprenorphine, any other medications, or any of the ingredients in a buprenorphine patch. Ask your doctor or pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take or use. Be sure to mention the medications listed in the IMPORTANT WARNING and any of the following medications: anticholinergics (atropine, belladonna, benztropine, dicyclomine, diphenhydramine, isopropamide, procyclidine, and scopolamine); certain medications for irregular heartbeat including amiodarone (Cordarone, Pacerone), disopyramide (Norpace), dofetilide (Tikosyn), procainamide (Procanbid), quinidine (in Nuedexta) and sotalol (Betapace, Betapace AF, Sorine); medications for seizures such as carbamazepine (Tegretol), phenobarbital, phenytoin (Dilantin, Phenytek); and rifampin (Rifadin, Rimactane). Your

doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor if you have or have ever had conditions mentioned in the IMPORTANT WARNING section or a paralytic ileus (condition in which digested food does not move through the intestines). Your doctor may tell you not to use buprenorphine patches.
- tell your doctor if you or an immediate family member have or have ever had prolonged QT syndrome (condition that increases the risk of developing an irregular heartbeat that may cause loss of consciousness, or sudden death); or if you have or ever had atrial fibrillation; heart failure; seizures; a head injury, a brain tumor, a stroke or any other condition that caused high pressure inside your skull; biliary tract disease; slowed heartbeat; low blood pressure; low blood levels of potassium; problems urinating; or pancreas, thyroid, heart, kidney, or liver disease.
- tell your doctor if you are breastfeeding.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are using a buprenorphine patch.
- you should know that this medication may make you drowsy. Do not drive a car, operate machinery, or do other possibly dangerous activities until you know how this medication affects you.
- you should know that buprenorphine patches may cause dizziness, lightheadedness, and fainting when you get up too quickly from a lying position. This is more common when you first start using a buprenorphine patch. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.
- do not drink any alcohol while using buprenorphine patches. Alcohol increases the chance that you will experience serious side effects of the medication.
- you should know that buprenorphine patches may cause constipation. Talk to your doctor about changing your diet or using other medications to prevent or treat constipation while you are using buprenorphine patches.
- you should know that if you have a fever or if you get very hot after physical activity, the amount of buprenorphine that you receive from the patch may increase and possibly cause an overdose of medication. Avoid physical activity that might cause you to get very hot. Call your doctor right away if you have a fever. Your doctor may need to adjust your dose.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you forget to apply or change a buprenorphine patch, apply the patch as soon as you remember it. Be sure to remove your used patch before applying a new patch. Wear the new patch for the period of time prescribed by your doctor (usually 7 days) and then replace it. Do

not wear two patches at once unless your doctor has told you that you should.

What side effects can this medication cause?

Buprenorphine patches may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- diarrhea
- difficulty falling asleep or staying asleep
- headache
- dizziness
- vomiting
- dry mouth
- stomach pain
- skin irritation, itching, swelling, or redness in the area where you wore the patch

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately or get emergency medical treatment:

- difficulty breathing or swallowing
- shortness of breath
- fast heartbeat
- chest pain
- swelling of your face, tongue or throat
- rash
- hives
- itching

Buprenorphine patches may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Throw away any patches that are used, outdated, or no longer needed by carefully removing the adhesive backing, folding the sticky sides of each patch together so that it sticks to itself, and flushing the patches down the toilet. You may also use a Patch Disposal Unit provided to you by the manufacturer to safely dispose of the unwanted patch in the trash. Wash your hands well with water after throwing away buprenorphine patches. Do not put unneeded or used buprenorphine patches in a garbage can. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include the following:

- small, pinpoint pupils (black circles in the center of the eye)
- extreme sleepiness or drowsiness
- slowed or difficulty breathing
- coma (loss of consciousness for a period of time)

What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else use your medication. Buprenorphine is a controlled substance. Prescriptions may be refilled only a limited number of times; ask your pharmacist if you have any questions.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Butrans[®]

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