

## MEDICATION GUIDE

### for BUTORPHANOL TARTRATE NASAL SPRAY USP, 10 mg/mL CIV

CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

#### What is the most important information I should know about Butorphanol Tartrate Nasal Spray USP?

- Your doctor has prescribed butorphanol tartrate nasal spray to treat your pain. The medication in butorphanol tartrate nasal spray belongs to a group of medicines that is known to cause dependence and abuse. Butorphanol tartrate nasal spray causes these effects only in a small number of patients. However, because it can have these effects, it is VERY IMPORTANT that you not use butorphanol tartrate nasal spray more often or in larger doses than your doctor has instructed. Also, it is important to have regular checkups with your doctor to ensure that you're using butorphanol tartrate nasal spray correctly. The longer you use butorphanol tartrate nasal spray, the greater your risk of getting dependent on it.
- Because butorphanol tartrate nasal spray may make you feel sleepy or dizzy, do not drive or operate dangerous machinery, e.g., automobiles until you can no longer feel the effects of the drug. Also, do not drink alcohol while using butorphanol tartrate nasal spray because it may worsen any side effects.

#### What is Butorphanol Tartrate Nasal Spray USP?

Butorphanol tartrate nasal spray is an opioid narcotic pain reliever that is used for the relief of pain when the use of an opioid pain medication is appropriate. Butorphanol tartrate nasal spray comes in the form of a nasal spray. One spray of butorphanol tartrate nasal spray is quickly absorbed in the nasal passages.

#### What do I need to know about using a strong opioid narcotic pain reliever such as Butorphanol Tartrate Nasal Spray USP?

Butorphanol tartrate nasal spray has been reported to be abused. Do not use butorphanol tartrate nasal spray more often or in larger doses than instructed by your doctor. Follow your doctor's instructions exactly and have regular checkups with your doctor when using butorphanol tartrate nasal spray to ensure you are using butorphanol tartrate nasal spray properly.

#### Who should not take Butorphanol Tartrate Nasal Spray USP?

Butorphanol tartrate nasal spray should not be used if you have ever had an allergic reaction to the active ingredient, butorphanol, or if you are allergic to benzethonium chloride, a preservative in butorphanol tartrate nasal spray. Butorphanol tartrate nasal spray should not be used by patients less than 18 years old. Butorphanol has been found in the breast milk of women who are using butorphanol tartrate nasal spray. Therefore, butorphanol tartrate nasal spray should not be used by patients who are breastfeeding. Patients over the age of 65 years may need less butorphanol tartrate nasal spray than younger patients.

You should not use butorphanol tartrate nasal spray if you are dependent on another narcotic medicine. Dependence is when you need the medicine and you can't perform normally unless you are taking it.

#### How should I take Butorphanol Tartrate Nasal Spray USP?

Use butorphanol tartrate nasal spray only as directed by your doctor. Never use butorphanol tartrate nasal spray more often or in larger doses than instructed by your doctor. Since you may experience sleepiness or dizziness, use butorphanol tartrate nasal spray in a comfortable location where you can lie down if necessary.

#### Usual Dosing

If your doctor prescribed a **1 mg dose** of butorphanol tartrate nasal spray for relief of pain:

- Spray **one spray** into **one** nostril – one spray is a 1 mg dose. This is the most common initial dose.

If prescribed by your doctor, a second spray may be taken 60 to 90 minutes after the first if needed for pain relief. If instructed by your doctor, the above sequence may be repeated every 3 to 4 hours as needed for pain relief. If your pain hasn't lessened or it becomes worse, please contact your doctor immediately.

If your doctor prescribed a **2 mg dose** of butorphanol tartrate nasal spray for relief of pain:

- Spray **one spray** in **each** nostril – two sprays equal a 2 mg dose. If instructed by your doctor, this dose of butorphanol tartrate nasal spray may be repeated every 3 to 4 hours as needed for pain relief. If your pain hasn't lessened or it becomes worse, please contact your doctor immediately.

If you have liver or kidney disease, you may need to take butorphanol tartrate nasal spray less often or in a lower dose. Elderly patients may also need to take a lower dose of butorphanol tartrate nasal spray.

### **Use and Storage of Nasal Spray Unit**

Your pharmacist will assemble the nasal spray unit. However, you must prime the unit before using it the first time and if it has not been used for 48 hours or longer. **NOTE: VIALS DO NOT APPEAR "FULL." THEY ARE PREFILLED TO DELIVER ON AVERAGE 14 TO 15 ONE (1) MG DOSES.** If you only use butorphanol tartrate nasal spray occasionally and need to reprime it each time, the vial will deliver an average of 8 to 10 doses of butorphanol tartrate nasal spray. **See additional instructions below for priming and using the spray unit.**

### **What should I avoid while taking Butorphanol Tartrate Nasal Spray USP?**

- Because butorphanol tartrate nasal spray may make you feel sleepy or dizzy, do not drive or operate dangerous machinery, e.g., automobiles until you no longer feel the effects of the drug.
- Do not drink alcohol while using butorphanol tartrate nasal spray because it may worsen drowsiness, dizziness and your general ability to function appropriately.
- Some medications cannot be taken with butorphanol tartrate nasal spray because of unwanted side effects. Before you begin using butorphanol tartrate nasal spray, as well as while you are using it, be sure to tell your doctor about any and all other drugs you are taking, including those sold without a prescription (over-the-counter). Do not take any other medicine, including any over-the-counter medicine, unless directed to do so by a doctor who knows you are using butorphanol tartrate nasal spray.
- Because butorphanol tartrate nasal spray may cause harm to an unborn child, tell your doctor if you are pregnant or planning to become pregnant.
- Because small amounts of butorphanol tartrate may appear in breast milk, be sure to consult with your doctor if you are nursing an infant.
- Because of butorphanol tartrate nasal spray's potential to cause dependence or abuse, be sure to tell your doctor if you ever had a problem with overuse of drugs or alcohol.

### **What are the possible side effects of Butorphanol Tartrate Nasal Spray USP?**

The type and frequency of side effects experienced by patients taking butorphanol tartrate nasal spray are those commonly seen with opioid narcotic pain relievers. The most frequently reported side effects in studies with butorphanol tartrate were drowsiness, dizziness, nausea and/or vomiting. In studies where patients used butorphanol tartrate nasal spray for up to 6 months, nasal congestion and difficulty sleeping were frequently reported.

Butorphanol tartrate nasal spray may affect your breathing. This side effect is serious but unlikely if butorphanol tartrate nasal spray is taken as instructed. Notify your doctor immediately if you experience shortness of breath or other difficulty breathing.

Butorphanol tartrate nasal spray may affect your blood pressure or your heart rate. **Notify your doctor immediately if you feel lightheaded, have an irregular heartbeat or have headaches that you did not have before you started taking butorphanol tartrate nasal spray.**

Side effects other than those listed above have occurred in some patients. For example, the following side effects have been reported rarely, but may be disturbing if they do occur: visual blurring, dysphoria (feeling of sadness, unpleasantness, or discomfort), floating feeling, and hallucinations. Notify your doctor or pharmacist if any side effects persist or become troublesome.

### **What do I do if someone takes an overdose of Butorphanol Tartrate Nasal Spray USP?**

If you suspect that someone may have taken an overdose of this medicine, contact your local poison control center or emergency room immediately.

This medication was prescribed for your current condition. Do not use butorphanol tartrate nasal spray for another condition or give the drug to others. Keep butorphanol tartrate nasal spray and all medicines out of the reach of children. Discard any unused portion of the medicine by removing the cap, rinsing the bottle and spray assembly under the water faucet, and disposing the parts in a waste can where children cannot easily get to them.

This summary does not include everything there is to know about butorphanol tartrate nasal spray. Medicines are sometimes prescribed for uses other than those listed. If you have questions or concerns, or want more information about butorphanol tartrate nasal spray, your doctor and pharmacist have the complete prescribing information upon which this guide is based. You may want to read it and discuss it with your doctor. Remember, no written summary can replace a careful discussion with your doctor.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Roxane Laboratories, Inc.  
Columbus, Ohio 43216

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