

MEDICATION GUIDE

Butorphanol Tartrate Nasal Spray, USP 10 mg/mL

(bue-TOR-fa-nol TAR-trate), 

Butorphanol Tartrate Nasal Spray is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about Butorphanol Tartrate Nasal Spray:

- **Get emergency help or call 911 right away if you take too much Butorphanol Tartrate Nasal Spray (overdose).** When you first start taking Butorphanol Tartrate Nasal Spray, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking Butorphanol Tartrate Nasal Spray 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.
- Never give anyone else your Butorphanol Tartrate Nasal Spray. They could die from taking it. Store Butorphanol Tartrate Nasal Spray away from children and in a safe place to prevent stealing or abuse. Selling or giving away Butorphanol Tartrate Nasal Spray is against the law.
- Never give anyone else your Butorphanol Tartrate Nasal Spray. They could die from taking it. Selling or giving away Butorphanol Tartrate Nasal Spray is against the law.
- Store Butorphanol Tartrate Nasal Spray securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take Butorphanol Tartrate Nasal Spray if you have:

- Severe asthma, trouble breathing, or other lung problems.
- A bowel blockage or have narrowing of the stomach or intestines.
- Previously had an allergic reaction to butorphanol or the preservative benzethonium chloride.

Before taking Butorphanol Tartrate Nasal Spray, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems.

Tell your healthcare provider if you are:

- **Pregnant or planning to become pregnant.** Prolonged use of Butorphanol Tartrate Nasal Spray during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **Breastfeeding.** Butorphanol Tartrate Nasal Spray passes into breast milk and may harm your baby.
- Living in a household where there are small children or someone who has abused street or prescription drugs
- Taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking Butorphanol Tartrate Nasal Spray with certain other medicines can cause serious side effects that could lead to death.

When taking Butorphanol Tartrate Nasal Spray:

- Do not change your dose. Take Butorphanol Tartrate Nasal Spray exactly as prescribed by your healthcare provider.
- See the detailed Patient Instructions for information about how to take Butorphanol Tartrate Nasal Spray. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose as instructed by your healthcare provider. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking Butorphanol Tartrate Nasal Spray regularly, do not stop taking Butorphanol Tartrate Nasal Spray without talking to your healthcare provider.
- After you stop taking Butorphanol Tartrate Nasal Spray, dispose of unused Butorphanol Tartrate Nasal Spray by unscrewing the cap, rinsing the bottle, and placing the parts in a waste container.

While taking Butorphanol Tartrate Nasal Spray DO NOT:

- Drive or operate heavy machinery, until you know how Butorphanol Tartrate Nasal Spray affects you. Butorphanol Tartrate Nasal Spray can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with Butorphanol Tartrate Nasal Spray may cause you to overdose and die.

The possible side effects of Butorphanol Tartrate Nasal Spray:

- Constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help or call 911 right away 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 Butorphanol Tartrate Nasal Spray. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information go to dailymed.nlm.nih.gov

This Medication Guide has been approved by the U.S. Food and Drug Administration.

KEEP OUT OF THE REACH OF CHILDREN.

APOTEX INC.

BUTORPHANOL TARTRATE NASAL SPRAY, USP 
10 mg/mL

Manufactured by
Apotex Inc.
Toronto, Ontario
Canada M9L 1T9

Manufactured for
Apotex Corp.
Weston, FL
USA 33326

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