PATIENT INSTRUCTIONS

for BUTORPHANOL TARTRATE NASAL SPRAY, USP 10 mg/mL (bue-TOR-fa-nol TAR-trate)

PATIENT INSTRUCTIONS

Take medication as directed by your physician. For proper use of the nasal spray, read the following instructions carefully.

NOTE: BOTTLES DO NOT APPEAR "FULL". THEY ARE PRE-FILLED TO DELIVER ON AVERAGE 14 TO 15 ONE (1) MG DOSES. (THE USUAL DOSE IS 1 MG-ONE SPRAY IN ONE NOSTRIL.)

THE UNIT MUST BE PRIMED WITH ONE OR TWO STROKES IF NOT USED FOR 48 HOURS OR LONGER.

Note: With intermittent use requiring repriming before each dose, the 2.5 mL bottle will deliver an average of 8 to 10 doses of butorphanol tartrate nasal spray.

When not in use, store spray unit in child-resistant container. Butorphanol tartrate nasal spray should not be used by anyone other than the person for whom it was prescribed. To prevent this, and to reduce the chance of children taking the drug it is important to dispose of any excess butorphanol tartrate nasal spray just as soon as it is no longer needed.

The best way to safely dispose of the unit is to unscrew the cap, rinse the bottle and spray assembly under the water faucet, and dispose of the parts in a waste can where children cannot easily get to them.

Figure 1



1. Blow nose gently to clear both nostrils.

Figure 2



2. Pull clear cover off pump unit. Remove protective clip from neck of pump unit.

Figure 3



3. Prime butorphanol tartrate nasal spray by placing nozzle between first and second finger with thumb on the bottom of bottle. Pump sprayer unit FIRMLY and QUICKLY until a fine spray appears (up to 7 to 8 strokes).

Figure 4



4. Insert spray tip approximately 1 cm (width of small finger) into one nostril, pointing the tip toward the back of the nose.

Figure 5



5. Close other nostril with your forefinger and tilt head slightly forward.

Figure 6



6. Pump spray unit firmly and quickly by pushing down on the "finger grips" of the pump unit and against the thumb at the bottom of the bottle. Sniff gently with your mouth closed.

Figure 7



- 7. After spraying, remove pump unit from nose. Tilt your head backwards and sniff gently a few more seconds.
- 8. Your doctor will tell you whether a two-spray dose is needed. If needed, administer a second spray in the other nostril, following steps 4 through 7. Replace protective clip and clear cover, respectively, (Fig. 2) after each dose.

USUAL DOSE: ONE Spray. Spray ONLY ONCE into ONLY ONE nostril. DO NOT spray into both nostrils unless directed by your doctor. DO NOT repeat sooner than directed by your doctor.

APOTEX INC.

BUTORPHANOL TARTRATE NASAL SPRAY, USP (1) mg/mL

Manufactured by Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for Apotex Corp. Weston, FL USA 33326

Revised: January 2021

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 (V) 10 mg/mL

Manufactured by Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for Apotex Corp. Weston, FL USA 33326

Revised: January 2021