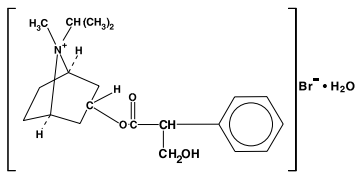
ATTENTION PHARMACIST: Detach "Patient's Instructions for Use" from package insert and dispense with product.

Atrovent®
(ipratropium bromide)
Nasal Spray 0.03%

Boehringer Ingelheim

Prescribing Information

DESCRIPTION
The active ingredient in ATROVENT® Nasal Spray is ipratropium bromide monohydrate. It is an anticholinergic agent chemically described as 8-azoniabicyclo (3.2.1) octane,3-(3-hydroxy-1-oxo-2-phenylpropoxy)-8-methyl-8-(1-methylethyl)-, bromide, monohydrate (*endo,syn*)-, (±)- :a synthetic quaternary ammonium compound, chemically related to atropine. Its structural formula is:



ipratropium bromide monohydrate — $C_{20}H_{30}BrNO_3 \cdot H_20$, Mol. Wt. 430.4

Ipratropium bromide is a white to off-white, crystalline substance. It is freely soluble in lower alcohols and water, existing in an ionized state in aqueous solutions, and relatively insoluble in non-polar media.

ATROVENT (ipratropium bromide) Nasal Spray 0.03% is a metered-dose, manual pump spray unit which delivers 21 mcg (70µL) ipratropium bromide per spray on an anhydrous basis in an isotonic, aqueous solution with pH adjusted to 4.7. It also contains benzalkonium chloride, edetate disodium, sodium chloride, sodium hydroxide, hydrochloric acid, and purified water. Each bottle contains 345 sprays.

CLINICAL PHARMACOLOGY
Mechanism of Action
Ipratropium bromide is an anticholinergic agent that inhibits vagally-mediated reflexes by antagonizing the action of acetylcholine at the cholinergic receptor. In humans, ipratropium bromide has anti-secretory properties and, when applied locally, inhibits secretions from the serous and seromucous glands lining the nasal mucosa. Ipratropium bromide is a quaternary amine that minimally crosses the nasal and gastrointestinal membrane and the blood-brain barrier, resulting in a reduction of the systemic anticholinergic effects (e.g., neurologic, ophthalmic, cardiovascular, and gastrointestinal effects) that are seen with tertiary anticholinergic amines.

Pharmacokinetics
Absorption: Ipratropium bromide is poorly absorbed into the systemic circulation following oral administration (2-3%). Less than 20% of an 84 mcg per nostril dose was absorbed from the nasal mucosa of normal volunteers, induced-cold patients, or perennial rhinitis patients.

Distribution: Ipratropium bromide is minimally bound (0 to 9% *in vitro*) to plasma albumin and α_1-acid glycoprotein. Its blood/plasma concentration ratio was estimated to be about 0.89. Studies in rats have shown that ipratropium bromide does not penetrate the blood-brain barrier.

Metabolism: Ipratropium bromide is partially metabolized to ester hydrolysis products, tropic acid and tropane. These metabolites appear to be inactive based on *in vitro* receptor affinity studies using rat brain tissue homogenates.

Elimination: After intravenous administration of 2 mg ipratropium bromide to 10 healthy volunteers, the terminal half-life of ipratropium was approximately 1.6 hours. The total body clearance and renal clearance were estimated to be 2,505 and 1,019 mL/min, respectively. The amount of the total dose excreted unchanged in the urine (Ae) within 24 hours was approximately one-half of the administered dose.

Pediatrics: Following administration of 42 mcg of ipratropium bromide per nostril two or three times a day in perennial rhinitis patients 6-18 years old, the mean amounts of the total dose excreted unchanged in the urine (8.6 to 11.1%) were higher than those reported in adult volunteers or adult perennial rhinitis patients (3.7 to 5.6%). Plasma ipratropium concentrations were relatively low (ranging from undetectable up to 0.49 ng/mL). No correlation of the amount of the total dose excreted unchanged in the urine (Ae) with age or gender was observed in the pediatric population.

Special Populations: Gender does not appear to influence the absorption or excretion of nasally administered ipratropium bromide. The pharmacokinetics of ipratropium bromide have not been studied in patients with hepatic or renal insufficiency or in the elderly.

Drug-Drug Interaction: No specific pharmacokinetic studies were conducted to evaluate potential drug-drug interactions.

Pharmacodynamics: In two single-dose trials (n=17), doses up to 336 mcg of ipratropium bromide did not significantly affect pupillary diameter, heart rate, or systolic/diastolic blood pressure. Similarly, in patients with induced-colds, ATROVENT (ipratropium bromide) Nasal Spray 0.06% (84 mcg/nostril four times a day), had no significant effects on pupillary diameter, heart rate or systolic/diastolic blood pressure.

Two nasal provocation trials in perennial rhinitis patients (n=44) using ipratropium bromide nasal spray showed a dose dependent increase in inhibition of methacholine induced nasal secretion with an onset of action within 15 minutes (time of first observation).

Controlled clinical trials demonstrated that intranasal fluorocarbon-propelled ipratropium bromide does not alter physiologic nasal functions (e.g., sense of smell, ciliary beat frequency, mucociliary clearance, or the air conditioning capacity of the nose).

Clinical Trials
The clinical trials for ATROVENT (ipratropium bromide) Nasal Spray 0.03% were conducted in patients with nonallergic perennial rhinitis (NAPR) and in patients with allergic perennial rhinitis (APR). APR patients were those who experienced symptoms of nasal hypersecretion and nasal congestion or sneezing when exposed to specific perennial allergens (e.g., dust mites, molds) and were skin test positive to these allergens. NAPR patients were those who experienced symptoms of nasal hypersecretion and nasal congestion or sneezing throughout the year, but were skin test negative to common perennial allergens.

In four controlled, four- and eight-week comparisons of ATROVENT (ipratropium bromide) Nasal Spray 0.03% (42 mcg per nostril, two or three times daily) with its vehicle, in patients with allergic or nonallergic perennial rhinitis, there was a statistically significant decrease in the severity and duration of rhinorrhea in the ATROVENT group throughout the entire study period. An effect was seen as early as the first day of therapy.

There was no effect of ATROVENT (ipratropium bromide) Nasal Spray 0.03% on degree of nasal congestion, sneezing, or postnasal drip. The response to ATROVENT (ipratropium bromide) Nasal Spray 0.03% did not appear to be affected by the type of perennial rhinitis (NAPR or APR), age, or gender. No controlled clinical trials directly compared the efficacy of BID versus TID treatment.

INDICATIONS AND USAGE
ATROVENT (ipratropium bromide) Nasal Spray 0.03% is indicated for the symptomatic relief of rhinorrhea associated with allergic and nonallergic perennial rhinitis in adults and children age 6 years and older. ATROVENT (ipratropium bromide) Nasal Spray 0.03% does not relieve nasal congestion, sneezing, or postnasal drip associated with allergic or nonallergic perennial rhinitis.

CONTRAINDICATIONS
ATROVENT (ipratropium bromide) Nasal Spray 0.03% is contraindicated in patients with a history of hypersensitivity to atropine or its derivatives, or to any of the other ingredients.

WARNINGS
Immediate hypersensitivity reactions may occur after administration of ipratropium bromide, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, and oropharyngeal edema.

PRECAUTIONS
General
ATROVENT (ipratropium bromide) Nasal Spray 0.03% should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy, or bladder neck obstruction, particularly if they are receiving an anticholinergic by another route. Cases of precipitation or worsening of narrow-angle glaucoma and acute eye pain have been reported with direct eye contact of ipratropium bromide administered by oral inhalation.

Information for Patients
Patients should be advised that temporary blurring of vision, precipitation or worsening of narrow-angle glaucoma, or eye pain may result if ATROVENT (ipratropium bromide) Nasal Spray 0.03% comes into direct contact with the eyes. Patients should be instructed to avoid spraying ATROVENT (ipratropium bromide) Nasal Spray 0.03% in or around their eyes. Patients who experience eye pain, blurred vision, excessive nasal dryness, or episodes of nasal bleeding should be instructed to contact their doctor. Patients should be reminded to carefully read and follow the accompanying Patient's Instructions for Use.

Drug Interactions
No controlled clinical trials were conducted to investigate drug-drug interactions. ATROVENT (ipratropium bromide) Nasal Spray 0.03% is minimally absorbed into the systemic circulation; nonetheless, there is some potential for an additive interaction with other concomitantly administered anticholinergic medications, including ATROVENT for oral inhalation.

Carcinogenesis, Mutagenesis, Impairment of Fertility
In two-year carcinogenicity studies in rats and mice, ipratropium bromide at oral doses up to 6 mg/kg (approximately 190 and 95 times the maximum recommended daily intranasal dose in adults, respectively, and approximately 110 and 60 times the maximum recommended daily intranasal dose in children, respectively, on a mg/m^2 basis) showed no carcinogenic activity. Results of various mutagenicity studies (Ames test, mouse dominant lethal test, mouse micronucleus test, and chromosome aberration of bone marrow in Chinese hamsters) were negative.

Fertility of male or female rats was unaffected by ipratropium bromide at oral doses up to 50 mg/kg (approximately 1,600 times the maximum recommended daily intranasal dose in adults on a mg/m^2 basis). At an oral dose of 500 mg/kg (approximately 16,000 times the maximum recommended daily intranasal dose in adults on a mg/m^2 basis), ipratropium bromide produced a decrease in the conception rate.

Pregnancy
TERATOGENIC EFFECTS Pregnancy Category B.
Oral reproduction studies were performed at doses of 10 mg/kg in mice, 1000 mg/kg in rats and 125 mg/kg in rabbits. These doses correspond, in each species respectively, to approximately 160, 32,000, and 8,000 times the maximum recommended daily intranasal dose in adults on a mg/m^2 basis. Inhalation reproduction studies were conducted in rats and rabbits at doses of 1.5 and 1.8 mg/kg, respectively, (approximately 50 and 120 times, respectively, the maximum recommended daily intranasal dose in adults on a mg/m^2 basis). These studies demonstrated no evidence of teratogenic effects as a result of ipratropium bromide. At oral doses above 90 mg/kg in rats (approximately 2,900 times the maximum recommended daily intranasal dose in adults on a mg/m^2 basis) embryotoxicity was observed as increased resorption. This effect is not considered relevant to human use due to the large doses at which it was observed and the difference in route of administration. However, no adequate or well controlled studies have been conducted in pregnant women. Because animal reproduction studies are not always predictive of human response, ATROVENT (ipratropium bromide) Nasal Spray 0.03% should be used during pregnancy only if clearly needed.

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PATIENT'S INSTRUCTIONS FOR USE

ATROVENT® (ipratropium bromide) Nasal Spray 0.03% is indicated for the symptomatic relief of rhinorrhea (runny nose) associated with allergic and nonallergic perennial rhinitis in adults and children age 6 years and older. ATROVENT (ipratropium bromide) Nasal Spray 0.03% does not relieve nasal congestion, sneezing, or postnasal drip associated with allergic or nonallergic perennial rhinitis. Read complete instructions carefully and use only as directed.

To Use:
1. Remove the clear plastic dust cap and the green safety clip from the nasal spray pump (Figure 1). The safety clip prevents the accidental discharge of the spray in your pocket or purse.

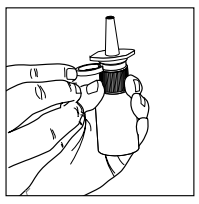
Figure 1

2. The nasal spray pump must be primed before ATROVENT (ipratropium bromide) Nasal Spray 0.03% is used for the first time. To prime the pump, hold the bottle with your thumb at the base and your index and middle fingers on the white shoulder area. Make sure the bottle points upright and away from your eyes. Press your thumb firmly and quickly against the bottle seven times (Figure 2). The pump is now primed and can be used. Your pump should not have to be reprimed unless you have not used the medication for more than 24 hours; repriming the pump will only require two sprays. If you have not used your nasal spray for more than seven days, repriming the pump will require seven sprays.


Figure 2

3. Before using ATROVENT (ipratropium bromide) Nasal Spray 0.03%, blow your nose gently to clear your nostrils if necessary.

4. Close one nostril by gently placing your finger against the side of your nose, tilt your head slightly forward and, keeping the bottle upright, insert the nasal tip into the other nostril (Figure 3). Point the tip toward the back and outer side of the nose.


Figure 3

5. Press firmly and quickly upwards with the thumb at the base while holding the white shoulder portion of the pump between your index and middle fingers. Following each spray, sniff deeply and breathe out through your mouth.

6. After spraying the nostril and removing the unit, tilt your head backwards for a few seconds to let the spray spread over the back of the nose.

7. Repeat steps 4 through 6 in the same nostril.

8. Repeat steps 4 through 7 in the other nostril (i.e., two sprays per nostril).

9. Replace the clear plastic dust cap and safety clip.

10. At some time before the medication is completely used up, you should consult your physician or pharmacist to determine whether a refill is needed. You should not take extra doses or stop using ATROVENT (ipratropium bromide) Nasal Spray 0.03% without consulting your physician.

To Clean:

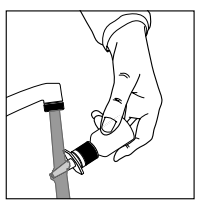
Figure 4

If the nasal tip becomes clogged, remove the clear plastic dust cap and safety clip. Hold the nasal tip under running, warm tap water (Figure 4) for about a minute. Dry the nasal tip, reprime the nasal spray pump (step 2 above), and replace the plastic dust cap and safety clip.

Caution:
ATROVENT (ipratropium bromide) Nasal Spray 0.03% is intended to relieve your rhinorrhea (runny nose) with regular use. It is therefore important that you use ATROVENT (ipratropium bromide) Nasal Spray 0.03% as prescribed by your physician. For most patients, some improvement in runny nose is usually apparent during the first full day of treatment with ATROVENT (ipratropium bromide) Nasal Spray 0.03%. Some patients may require up to two weeks of treatment to obtain maximum benefit.

Product + component:	Atrovent Nasal Spray, 0.03% / leaflet
Art. No.:	10001900/US/1
Country:	United States
Dimension:	6.25" x 15"
Scale:	1:1 (inches)
Date:	25. November 2002
Colours:	Black
No. of Films:	2 (Side 1)
Manufacturer:	Roxane Laboratories, Inc.
No. of Code:	Interleaved 2of5 Barcode
Sales / Samples:	Sales

Notes:
- Barcode = For position only; Interleaved 2of5; barcode prints 100% Black; Encodation: 10001900 ; Magnification: 53.5%
- Perforation does not get printed.

Approvals

Signature(s):	Department:	Date: m/d/y
	Graphics	
	Engineer	
	DRA	
	Marketing	
	Legal	
	DSI	
	Medical	

Perforation

Do not spray ATROVENT® (ipratropium bromide) Nasal Spray 0.03% in your eyes. Should this occur, immediately flush your eye with cool tap water for several minutes. If you accidentally spray ATROVENT (ipratropium bromide Nasal Spray 0.03% in your eyes, you may experience a temporary blurring of vision and increased sensitivity to light, which may last a few hours. Should eye pain or blurred vision occur, contact your doctor.

Should you experience excessive nasal dryness or episodes of nasal bleeding contact your doctor.

You should not use this drug if you have glaucoma or difficult urination due to an enlargement of the prostate, unless directed by a physician. ATROVENT (ipratropium bromide) Nasal Spray 0.03% should not be used during pregnancy or breast feeding unless directed by a physician. It is not known whether ipratropium bromide is excreted in human milk; however, many drugs are excreted in human milk.

Storage:
Store tightly closed between 59°F (15°C) and 86°F (30°C). Avoid freezing. Keep out of reach of children.

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Pharmaceuticals, Inc.
Ridgefield, CT 06877

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Boehringer Ingelheim
International GmbH

U.S. Patent No. 4,385,048

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10001900/US/1 10001900/01

Nursing Mothers
It is known that some ipratropium bromide is systemically absorbed following nasal administration; however the portion which may be excreted in human milk is unknown. Although lipid-insoluble quaternary bases pass into breast milk, the minimal systemic absorption makes it unlikely that ipratropium bromide would reach the infant in an amount sufficient to cause a clinical effect. However, because many drugs are excreted in human milk, caution should be exercised when ATROVENT® (ipratropium bromide) Nasal Spray 0.03% is administered to a nursing woman.

Pediatric Use
The safety of ATROVENT (ipratropium bromide) Nasal Spray 0.03% at a dose of two sprays (42 mcg) per nostril two or three times daily (total dose 168 to 252 mcg/day) has been demonstrated in 77 pediatric patients 6-12 years of age in placebo-controlled, 4-week trials and in 55 pediatric patients in active-controlled, 6 month trials. The effectiveness of ATROVENT (ipratropium bromide) Nasal Spray 0.03% for the treatment of rhinorrhea associated with allergic and nonallergic perennial rhinitis in this pediatric age group is based on an extrapolation of the demonstrated efficacy of ATROVENT (ipratropium bromide) Nasal Spray 0.03% in adults with these conditions and the likelihood that the disease course, pathophysiology, and the drug's effects are substantially similar to that of the adults. The recommended dose for the pediatric population is based on within and cross-study comparisons of the efficacy of ATROVENT (ipratropium bromide) Nasal Spray 0.03% in adults and pediatric patients and on its safety profile in both adults and pediatric patients. The safety and effectiveness of ATROVENT (ipratropium bromide) Nasal Spray 0.03% in patients under 6 years of age have not been established.

ADVERSE REACTIONS
Adverse reaction information on ATROVENT (ipratropium bromide) Nasal Spray 0.03% in patients with perennial rhinitis was derived from four multicenter, vehicle-controlled clinical trials involving 703 patients (356 patients on ATROVENT and 347 patients on vehicle), and a one-year, open-label, follow-up trial. In three of the trials, patients received ATROVENT (ipratropium bromide) Nasal Spray 0.03% three times daily, for eight weeks. In the other trial, ATROVENT (ipratropium bromide) Nasal Spray 0.03% was given to patients two times daily for four weeks. Of the 285 patients who entered the open-label, follow-up trial, 232 were treated for 3 months, 200 for 6 months, and 159 up to one year. The majority (>86%) of patients treated for one year were maintained on 42 mcg per nostril, two or three times daily, of ATROVENT (ipratropium bromide) Nasal Spray 0.03%.

The following table shows adverse events, and the frequency that these adverse events led to the discontinuation of treatment, reported for patients who received ATROVENT (ipratropium bromide) Nasal Spray 0.03% at the recommended dose of 42 mcg per nostril, or vehicle two or three times daily for four or eight weeks. Only adverse events reported with an incidence of at least 2.0% in the ATROVENT group and higher in the ATROVENT group than in the vehicle group are shown.

% of Patients Reporting Events+

	ATROVENT Nasal spray 0.03% (n=356)		Vehicle Control (n=347)	
	Incidence %	Discontinued %	Incidence %	Discontinued %
Headache	9.8	0.6	9.2	0
Upper respiratory tract infection	9.8	1.4	7.2	1.4
Epistaxis[1]	9.0	0.3	4.6	0.3
Rhinitis*				
Nasal dryness	5.1	0	0.9	0.3
Nasal irritation[2]	2.0	0	1.7	0.6
Other nasal symptoms[3]	3.1	1.1	1.7	0.3
Pharyngitis	8.1	0.3	4.6	0
Nausea	2.2	0.3	0.9	0

+ This table includes adverse events which occurred at an incidence rate of at least 2.0% in the ATROVENT group and more frequently in the ATROVENT group than in the vehicle group.
1 Epistaxis reported by 7.0% of ATROVENT patients and 2.3% of vehicle patients, blood-tinged mucus by 2.0% of ATROVENT patients and 2.3% of vehicle patients.
2 Nasal irritation includes reports of nasal itching, nasal burning, nasal irritation, and ulcerative rhinitis.
3 Other nasal symptoms include reports of nasal congestion, increased rhinorrhea, increased rhinitis, posterior nasal drip, sneezing, nasal polyps, and nasal edema.
* All events are listed by their WHO term; rhinitis has been presented by descriptive terms for clarification.

ATROVENT (ipratropium bromide) Nasal Spray 0.03% was well tolerated by most patients. The most frequently reported nasal adverse events were transient episodes of nasal dryness or epistaxis. These adverse events were mild or moderate in nature, none was considered serious, none resulted in hospitalization and most resolved spontaneously or following a dose reduction. Treatment for nasal dryness and epistaxis was required infrequently (2% or less) and consisted of local application of pressure or a moisturizing agent (e.g., petroleum jelly or saline nasal spray). Patient discontinuation for epistaxis or nasal dryness was infrequent in both the controlled (0.3% or less) and one-year, open-label (2% or less) trials. There was no evidence of nasal rebound (i.e., a clinically significant increase in rhinorrhea, posterior nasal drip, sneezing or nasal congestion severity compared to baseline) upon discontinuation of double-blind therapy in these trials.

Adverse events reported by less than 2% of the patients receiving ATROVENT (ipratropium bromide) Nasal Spray 0.03% during the controlled clinical trials or during the open-label follow-up trial, which are potentially related to ATROVENT's local effects or systemic anticholinergic effects include: dry mouth/throat, dizziness, ocular irritation, blurred vision, conjunctivitis, hoarseness, cough, and taste perversion.

Additional anticholinergic effects noted with other ATROVENT dosage forms (ATROVENT Inhalation Solution, ATROVENT Inhalation Aerosol, and ATROVENT Nasal Spray 0.06%) include: precipitation or worsening of narrow angle glaucoma, urinary retention, prostatic disorders, tachycardia, constipation, and bowel obstruction.

There were infrequent reports of skin rash in both the controlled and uncontrolled clinical studies. Allergic-type reactions such as skin rash, angioedema of the throat, tongue, lips and face, generalized urticaria, laryngospasm, and anaphylactic reactions have been reported with ATROVENT Nasal Spray 0.03% and other ipratropium bromide products.

OVERDOSAGE
Acute overdosage by intranasal administration is unlikely since ipratropium bromide is not well absorbed systemically after intranasal or oral administration. Following administration of a 20 mg oral dose (equivalent to ingesting more than four bottles of ATROVENT Nasal Spray 0.03%) to 10 male volunteers, no change in heart rate or blood pressure was noted. Following a 2 mg intravenous infusion over 15 minutes to the same 10 male volunteers, plasma ipratropium concentrations of 22-45 ng/mL were observed (>100 times the concentrations observed following intranasal administration). Following intravenous infusion these 10 volunteers had a mean increase of heart rate of 50 bpm and less than 20 mmHg change in systolic or diastolic blood pressure at the time of peak ipratropium levels.

Oral median lethal doses of ipratropium bromide were greater than 1,000 mg/kg in mice (approximately 16,000 and 9,500 times the maximum recommended daily intranasal dose in adults and children, respectively, on a mg/m^2 basis), 1,700 mg/kg in rats (approximately 55,000 and 32,000 times the maximum recommended daily intranasal dose in adults and children, respectively, on a mg/m^2 basis), and 400 mg/kg in dogs (approximately 43,000 and 25,000 times the maximum recommended daily intranasal dose in adults and children, respectively, on a mg/m^2 basis).

DOSAGE AND ADMINISTRATION
The recommended dose of ATROVENT (ipratropium bromide) Nasal Spray 0.03% is two sprays (42 mcg) per nostril two or three times daily (total dose 168 to 252 mcg/day) for the symptomatic relief of rhinorrhea associated with allergic and nonallergic perennial rhinitis in adults and children age 6 years and older. Optimum dosage varies with the response of the individual patient. Initial pump priming requires seven sprays of the pump. If used regularly as recommended, no further priming is required. If not used for more than 24 hours, the pump will require two sprays, or if not used for more than seven days, the pump will require seven sprays to reprime.

HOW SUPPLIED
ATROVENT (ipratropium bromide) Nasal Spray 0.03% is supplied in a white high density polyethylene (HDPE) bottle fitted with a white and clear metered nasal spray pump, a green safety clip to prevent accidental discharge of the spray, and a clear plastic dust cap. It contains 31.1g of product formulation, 345 sprays, each delivering 21 mcg (70µL) of ipratropium per spray, or 28 days of therapy at the maximum recommended dose (two sprays per nostril three times a day).

Store tightly closed between 59°F (15°C) and 86°F (30°C). Avoid freezing. Keep out of reach of children. Do not spray in the eyes.

Patients should be reminded to read and follow the accompanying Patient's Instructions for Use, which should be dispensed with the product.

℞ only

Boehringer Ingelheim Pharmaceuticals, Inc.
Ridgefield, CT 06877

Licensed from: Boehringer Ingelheim International GmbH

U.S. Patent No. 4,385,048

Rev. Nov 14, 2002
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Perforation

Product + component:	Atrovent Nasal Spray, 0.03% / leaflet
Art. No.:	10001900/US/1
Country:	United States
Dimension:	6.25" x 15"
Scale:	1:1 (inches)
Date:	25. November 2002
Colours:	Black ■
No. of Films:	2 (Side 2)
Manufacturer:	Roxane Laboratories, Inc.
No. of Code:	Interleaved 2of5 Barcode
Sales / Samples:	Sales

Notes:
- Barcode = For position only; Interleaved 2of5; barcode prints 100% Black; Encodation: 10001900 ; Magnification: 53.5%
- Perforation does not get printed.

Approvals

Signature(s):	Department:	Date: m/d/y
	Graphics	
	Engineer	
	DRA	
	Marketing	
	Legal	
	DSI	
	Medical	