



LABEL: ATROVENT HFA- ipratropium bromide aerosol, metered

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NDC Code(s): 0597-0087-17

Packager: Boehringer Ingelheim Pharmaceuticals, Inc.

Category: HUMAN PRESCRIPTION DRUG LABEL

DEA Schedule: None

Marketing Status: New Drug Application

DRUG LABEL INFORMATION

Updated October 5, 2023

If you are a consumer or patient please visit [this version](#).

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ATROVENT HFA safely and effectively. See full prescribing information for ATROVENT HFA. ATROVENT® HFA (ipratropium bromide HFA ...

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1 INDICATIONS AND USAGE

ATROVENT HFA Inhalation Aerosol is indicated as a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic ...

2 DOSAGE AND ADMINISTRATION

The usual starting dose of ATROVENT HFA is two inhalations four times a day. Patients may take additional inhalations as required; however, the total number of inhalations should not exceed 12 in ...

3 DOSAGE FORMS AND STRENGTHS

ATROVENT HFA is an inhalation aerosol supplied in a pressurized stainless steel canister as a metered-dose inhaler with a white mouthpiece that has a clear, colorless sleeve and a green protective ...

4 CONTRAINDICATIONS

ATROVENT HFA is contraindicated in the following conditions [see Warnings and Precautions (5.2)]. Hypersensitivity to ipratropium bromide or other ATROVENT HFA components - Hypersensitivity to ...

5 WARNINGS AND PRECAUTIONS

5.1 Use for Maintenance Treatment Only - ATROVENT HFA is a bronchodilator for the maintenance treatment of bronchospasm associated with COPD and is not indicated for the initial treatment of ...

6 ADVERSE REACTIONS

The following adverse reactions are described, or described in greater detail, in other sections: Hypersensitivity Reactions, Including Anaphylaxis [see Contraindications (4) and Warnings and ...

7 DRUG INTERACTIONS

ATROVENT HFA has been used concomitantly with other drugs, including sympathomimetic bronchodilators, methylxanthines, oral and inhaled steroids commonly used in the treatment of COPD. With the ...

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy - Risk Summary - Ipratropium is negligibly absorbed systemically following oral inhalation; therefore, maternal use is not expected to result in fetal exposure to the drug [see ...

10 OVERDOSAGE

Acute overdose by inhalation is unlikely since ipratropium bromide is not well absorbed systemically after inhalation or oral administration.

11 DESCRIPTION

The active ingredient in ATROVENT HFA is ipratropium bromide (as the monohydrate). It is an anticholinergic bronchodilator chemically described as 8-azoniabicyclo[3.2.1]octane ...

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action - Ipratropium bromide is an anticholinergic (parasympatholytic) agent which, based on animal studies, appears to inhibit vagally-mediated reflexes by antagonizing the ...

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility - Two-year oral carcinogenicity studies in rats and mice have revealed no carcinogenic activity at doses up to 6 mg/kg (approximately 240 ...

14 CLINICAL STUDIES

Conclusions regarding the efficacy of ATROVENT HFA were derived from two randomized, double-blind, controlled clinical studies. These studies enrolled males and females ages 40 years and older ...

16 HOW SUPPLIED/STORAGE AND HANDLING

ATROVENT HFA is supplied in a pressurized stainless steel canister as a metered-dose inhaler with a white mouthpiece that has a clear, colorless sleeve and a green protective cap (NDC ...

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Instructions for Use). Appropriate and safe use of ATROVENT HFA includes providing the patient with the information listed below and ...

SPL UNCLASSIFIED SECTION

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INSTRUCTIONS FOR USE

ATROVENT® HFA - (ipratropium bromide HFA) Inhalation Aerosol, for oral inhalation use - Read this Instructions for Use before using your ATROVENT HFA and each time you get a refill. There may be new ...

PRINCIPAL DISPLAY PANEL - 17 MCG CANISTER CARTON

NDC 0597-0087-17 - Atrovent® HFA - (ipratropium bromide HFA - inhalation aerosol) 17 mcg/actuation - Each actuation delivers 17 mcg ipratropium - bromide from the mouthpiece. Rx only - with Dose ...

INGREDIENTS AND APPEARANCE

Product Information

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