Skip to main content

Albuterol Sulfate Inhalation Aerosol (Ventolin HFA)

??? ??????: 30 ??????/?????? 2017

Use of VENTOLIN HFA (albuterol sulfate inhalation aerosol) may be associated with the following:

-]**PRECAUTIONS** and**WARNINGS** Paradoxical bronchospasm [see
-]**PRECAUTIONS** and**WARNINGS** Cardiovascular effects [see
-]**PRECAUTIONS** and**WARNINGS** Immediate hypersensitivity reactions [see
-]**PRECAUTIONS** and**WARNINGS** Hypokalemia [see

Clinical Trials Experience

The safety data described below reflects exposure to VENTOLIN HFA (albuterol sulfate inhalation aerosol) in 248 patients treated with VENTOLIN HFA (albuterol sulfate inhalation aerosol) in 3 placebo-controlled clinical trials of 2 to 12 weeks' duration. The data from adults and adolescents is based upon 2 clinical trials in which 202 patients with asthma 12 years of age and older were treated with VENTOLIN HFA (albuterol sulfate inhalation aerosol) 2 inhalations 4 times daily for 12 weeks' duration. The adult/adolescent population was 92 female, 110 male and 163 white, 19 black, 18 Hispanic, 2 other. The data from pediatric patients are based upon 1 clinical trial in which 46 patients with asthma 4 to 11 years of age were treated with VENTOLIN HFA (albuterol sulfate inhalation aerosol) 2 inhalations 4 times daily for 2 weeks' duration. The population was 21 female, 25 male and 25 white, 17 black, 3 Hispanic, 1 other.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

: The two 12-week, randomized, double-blind studies in 610 adolescent and adult patients with asthma that **Adults and Adolescents 12 Years of Age and Older** compared VENTOLIN HFA (albuterol sulfate inhalation aerosol) , a CFC 11/12-propelled albuterol inhaler, and an HFA-134a placebo inhaler. Overall, the incidence and nature of the adverse reactions reported for VENTOLIN HFA (albuterol sulfate inhalation aerosol) and a CFC 11/12-propelled albuterol inhaler were comparable. Table 1 lists the incidence of all adverse reactions (whether considered by the investigator to be related or unrelated to drug) from these studies that occurred at a rate of 3% or greater in the group treated with VENTOLIN HFA (albuterol sulfate inhalation aerosol) and more frequently in the group treated with VENTOLIN HFA (albuterol sulfate inhalation aerosol) than in the HFA-134a placebo inhaler group.

***Table 1. Overall Adverse Reactions With ? 3% Incidence in 2 Large 12-Week Clinical Trials in Adolescents and Adults**

Adverse Reaction	Percent of Patients		
	VENTOLIN HFA (albuterol sulfate inhalation aerosol) (n = 202) %	CFC 11/12-Propelled Albuterol Inhaler (n = 207) %	Placebo HF-134a (n = 201) %
Ear, nose<, and throat			
Throat irritation	10	6	7
Upper respiratory inflammation	5	5	2
Lower respiratory			
Viral respiratory infections	7	4	4
Cough	5	2	2
Musculoskeletal			
Musculoskeletal pain	5	5	4

* This table includes all adverse reactions (whether considered by the investigator to be drug-related or unrelated to drug) that occurred at an incidence rate of at least 3.0% in the group treated with VENTOLIN HFA and more frequently in the group treated with VENTOLIN HFA than in the HFA-134a placebo inhaler group.

Adverse reactions reported by less than 3% of the adolescent and adult patients receiving VENTOLIN HFA (albuterol sulfate inhalation aerosol) and by a greater proportion of patients receiving VENTOLIN HFA than receiving HFA-134a placebo inhaler and that have the potential to be related to VENTOLIN HFA (albuterol sulfate inhalation aerosol) include diarrhea, laryngitis, oropharyngeal edema, cough, lung disorders, tachycardia, and extrasystoles. Palpitation and dizziness have also been observed with VENTOLIN HFA (albuterol sulfate inhalation aerosol) .

Pediatric Patients : Results from the 2-week pediatric clinical study in patients with asthma 4 to 11 years of age showed that this pediatric population had an adverse reaction profile similar to that of the adolescent and adult populations.

Three studies have been conducted to evaluate the safety and efficacy of VENTOLIN HFA in patients between birth and 4 years of age. The results of these studies . Since the efficacy of VENTOLIN HFA *[see Pediatric Use]*did not establish the efficacy of VENTOLIN HFA (albuterol sulfate inhalation aerosol) in this age-group (albuterol sulfate inhalation aerosol) has not been demonstrated in children between birth and 48 months of age, the safety of VENTOLIN HFA (albuterol sulfate inhalation aerosol) in this age-group cannot be established. However, the safety profile observed in the pediatric population under 4 years of age was comparable to that observed in the older pediatric patients and in adolescents and adults. Where adverse reaction incidence rates were greater in patients under 4 years of age compared with older patients, the higher incidence rates were noted in all treatment arms, including placebo. These adverse reactions included upper respiratory tract infection, nasopharyngitis, pyrexia, and tachycardia.

Postmarketing Experience

In addition to the adverse reactions listed in section 6.1, the following adverse reactions have been identified during postapproval use of VENTOLIN HFA (albuterol sulfate inhalation aerosol) . Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Cases of paradoxical bronchospasm, hoarseness, arrhythmias (including atrial fibrillation, supraventricular tachycardia), and hypersensitivity reactions (including urticaria, angioedema, rash) have been reported after the use of VENTOLIN HFA (albuterol sulfate inhalation aerosol) .

In addition, albuterol, like other sympathomimetic agents, can cause adverse reactions such as hypokalemia, hypertension, peripheral vasodilatation, angina, tremor, central nervous system stimulation, hyperactivity, sleeplessness, headache, muscle cramps, and drying or irritation of the oropharynx.