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Budesonide (Rhinocort Aqua)

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

Systemic and intranasal corticosteroids use may result in the following:

-].**WARNINGS AND PRECAUTIONS** infection, nasal septum perforation, and impaired wound healing [see *Candida albicans* Epistaxis,
-].**WARNINGS AND PRECAUTIONS** Hypersensitivity Including Anaphylaxis [see
-].**WARNINGS AND PRECAUTIONS** Immunosuppression [see
-].**WARNINGS AND PRECAUTIONS** Hypercorticism and Adrenal Suppression [see
-].**Use in Specific Populations** and **WARNINGS AND PRECAUTIONS** Growth Effect [see
-].**WARNINGS AND PRECAUTIONS** Glaucoma and Cataracts [see

Clinical Trials Experience

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 incidence of common adverse reactions in Table 1 is based upon two U.S. and five non-U.S. controlled clinical trials in 1,526 patients with seasonal or perennial rhinitis in adults and children ? 6 years treated with RHINOCORT AQUA (budesonide) Nasal Spray at doses up to 400 mcg once daily for 3-6 weeks. This population included 745 females and 781 males with a mean age of 31 years (range of 6-85 years, 349 were 6 < 18 years). The racial distribution of patients receiving RHINOCORT AQUA (budesonide) Nasal Spray was 93% white, 3% black and 4% other. Table 1 describes adverse reactions occurring at an incidence of 2% or greater and more commonly among RHINOCORT AQUA (budesonide) Nasal Spray-treated patients than in placebo-treated patients in controlled clinical trials.

Table 1. Adverse Reactions occurring at an incidence ? 2% and more commonly than placebo in the RHINOCORT AQUA (budesonide) Nasal Spray group in patients 6 years and older

Placebo Vehicle	RHINOCORT AQUA Nasal Spray	Adverse Event
5%	8%	Epistaxis
3%	4%	Pharyngitis
1%	2%	Bronchospasm
< 1%	2%	Coughing
< 1%	2%	Nasal Irritation

A similar adverse reaction profile was observed in the subgroup of pediatric patients 6 to 12 years of age. These patients are included in Table 1.

Two to three percent (2-3%) of patients in clinical trials discontinued because of adverse reactions. Systemic corticosteroid side effects were not reported during controlled clinical studies with RHINOCORT AQUA (budesonide) Nasal Spray.

If recommended doses are exceeded, or if individuals are particularly sensitive, symptoms of hypercorticism, ie, Gushing's Syndrome, and adrenal suppression could occur.

Post-marketing Experience

The following adverse reactions have been reported during post-approval use of RHINOCORT AQUA (budesonide) Nasal Spray. 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.

immediate and delayed hypersensitivity reactions (including anaphylactic reaction, urticaria, rash, dermatitis, angioedema and pruritus),***Immune system disorders:***
]**CONTRAINDICATIONS** and **WARNINGS AND PRECAUTIONS** [see

]**WARNINGS AND PRECAUTIONS** glaucoma, increased intraocular pressure, cataracts [see ***Eye disorders:***

nasal septum perforation, anosmia, pharynx disorders (throat irritation, throat pain, swollen throat, burning ***Respiratory, thoracic, and mediastinal disorders:***

throat, and itchy throat), and wheezing

palpitations ***Cardiac disorders:***

]**Use In Specific Populations** and **WARNINGS AND PRECAUTIONS** growth suppression [see ***Musculoskeletal and connective tissue disorders:***