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For product information, please log-on to the web site www.nasacort.com or contact one of our Medical Information Specialists at (800) 633-1610.

Proprietary Drug Name: NASACORT® AQ Nasal Spray	**INN:** Triamcinolone Acetonide Nasal Spray	**Therapeutic area and FDA approved indications:** For the treatment of nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 6 years of age and older.
Name of Sponsor/Company:	Aventis Pharmaceuticals,Inc., Member of the sanofi-aventis group	

Title of Study: (XRG 5029C/1000) An open-label, repeat-dose, multicenter study to evaluate the safety and pharmacokinetics of single and multiple doses of intranasally administered triamcinolone acetonide (NASACORT® AQ) in pediatric allergic rhinitis patients 2 to 5 years of age compared with adult patients 18 to 50 years of age.

Principal Study Investigators: James Connor, MD
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4094, Fourth Ave, Suite 201
San Doiego, CA 92103

Study centre(s): 6 US sites

Publication: Cooper PD, Coner JD, Mustillo P, Sekar V, Garcia J, Georges G, Kovacs SJ. Pharmacokinetics and short-term safety and tolerability of intranasally administered triamcinolone acetonide aqueous spray in 2-5 year old patients with perennial allergic rhinitis (PAR) and adult patients with PAR. *J Allergy Clin Immunol*. 2005;115(2):S133.

Studied period (years): (date of first enrolment) (date of last completed): 30 April, 2003 to 22 March, 2004	**Phase of development:** Phase I

Objectives: To characterize the single dose and steady-state pharmacokinetics of triamcinolone acetonide (TAA) in pediatric subjects 2 to 5 years of age compared with adult sugjects 18 to 50 years of age following 5 days of intranasal dose administration

To evaluate the safety and tolerability of 5 days of intranasal TAA in pediatric subjects
Methodology: open-label, repeat-dose, multicenter study with one treatment period for pediatric subjects and two treatment periods for adult subjects
Number of patients (planned and analyzed): 24 subjects planned; 30 Enrolled, and 28 completed
Diagnosis and main criteria for inclusion: • Male and female pediatric (2 to 5 years of age) or adult subjects (18 to 50 years of age) with PAR with or without SAR • Positive skin prick test to a perennial allergen or documented positive skin prick test performed within 1 year of the first dose of TAA in adult subjects or a clinical diagnosis of PAR in pediatric subjects • Morning serum cortisol (≥5 µg/dL [138 nmol/L]) confirmed by immunoassay

Test product, dose and mode of administration, batch number:

Peds: Nasacort® AQ 110µg qd for 5 days intranasally

Adults: Nasacort® AQ 110µg qd for 5 days, a 7-day washout period, followed by 220 µg qd intranasally for 5 days

Lot number MN7046.

Duration of treatment:

Peds: 5 days

Adults: 10 days total of adults (TAA 110µg qd for 5 days, A 7-day washout period, followed by 220 µg qd intranasally for 5 days)

Reference therapy, dose and mode of administration, batch number:

Matching placebo nasal spray, lot number N10103B and 30091A

Criteria for evaluation:

Efficacy: Pharmacokinetic data- plasma sample analysis for TAA concentration

Safety: adverse events, laboratory data (hematology, serum chemistry, and urinalysis), physicial examination, and vital signs

Statistical methods: Continuous data were summarized descriptively as the number of subjects, mean, standard deviation, coefficient of variation, median, minimum and maximum. Categorical data were summarized as the number of subjects and percentage of subjects in each category.

SUMMARY – CONCLUSIONS

EFFICACY RESULTS: In the pediatric subjects with allergic rhinitis, as in adults, the pharmacokinetics of TAA following intranasal administration of Nasacort® AQ (TAA) can be described by a one-compartment model with first order input. The estimated CL/F of TAA is lower in the 2 to 5 year olds, but the inter-subject variability in CL/F is moderate and similar between pediatric and adult subjects. A daily dose of 110 µg administered intra nasally to 2 to 5 year olds with allergic rhinitis can be expected to best target and match the systemic exposures to TAA produced by a daily dose of 220 µg administered intranasally to adults.

SAFETY RESULTS: There was no clinical or laboratory evidence of adverse system effects of TAA, including HPA-axis suppression, following short-term treatment. A 5-day course of TAA 110 µg administered intra nasally to 2 to 5 year old pediatric subjects with PAR was generally safe and well tolerated. Similarly, two separate 5 day courses of either TAA 110 µg or TAA 220 µg administered intra nasally to adult subjects with PAR was also safe and well tolerated. There was no apparent difference in the type, number, duration, severity, or resolution of TEAEs between doses (110 µg vs 220 µg dose) in adult subjects. The overall profile of adverse events observed in all subjects studied was consistent with the known adverse events associated with the use of Nasacort® AQ.

Date of the report: 18 August, 2005