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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 sanof-aventis group

Title of Study: (XRG5029C/4005). Open-label study of the quality of sleep in allergic rhinitis (QOSAR) following treatment with triamcinolone acetonide nasal spray in a primary care setting

Principal Study Investigators:

Study centre(s): 144 US centers

Publication:

Mintz M, Garcia J, Diener P, Liao Y, Dupclay L, Georges G. Triamcinolone acetonide aqueous nasal spray improves nocturnal rhinitis-related quality of life in patients treated in a primary care setting: the Quality of Sleep in Allergic Rhinitis study. *Ann Allergy Asthma Immunol.* 2004 Feb;92(2):255-61.

Study period (years): (date of first enrolment) (date of last completed): 22 Mar, 2002 to 18 Oct, 2002	**Phase of development:** Phase IV

Objectives: The objective of this study was to assess subject-reported nocturnal rhinitis-related quality of life using the Nocturnal Rhinitis Quality of Life Questionnaire (NRQLQ) and sleep disturbance using the Pittsburgh Sleep Quality Index (PSQI) in allergic rhinitis (seasonal and/or perennial) subjects treated with once-daily Nasacort® AQ 220 mcg in a primary care setting.

Methodology: The study was an open-label study in subjects with seasonal and/or perennial allergic rhinitis. Subjects who met all inclusion and no exclusion criteria at Visit 1 (Day 1) were

treated with Nasacort® AQ 220 mcg once daily for 3 weeks. The NRQLQ and the PSQI were collected at Visit 1 (baseline) and at Visit 2 (after 21 ± 3 days of treatment).
Number of patients (planned and analyzed): 1000 patients were planned . A total of 651 subjects participated at 144 sites. Of the 651 subjects, 590 (91%) completed the study and 61 discontinued.
Diagnosis and main criteria for inclusion: Subjects, male or female, aged 18 and older, who were diagnosed by the investigator to require treatment with intranasal corticosteroids. Subjects could not be on intranasal corticosteroids at the time of study entry and could not have not taken intranasal corticosteroids for at least 1 month prior to Day 1 (Visit 1).
Test product, dose and mode of administration, batch number: Nasacort® AQ Nasal Spray, 220µg (2 sprays / nostril once daily), batch number not available
Duration of treatment: 21 ± 3 days.
Reference therapy, dose and mode of administration, batch number: none
Criteria for evaluation: Efficacy: The validated NRQLQ was used in a primary care setting to measure nocturnal rhinitis-related quality of life in subjects using Nasacort® AQ 220 mcg. Sleep disturbance was measured by the PSQI. Safety: Safety was assessed by monitoring study-emergent clinical adverse events (AEs).
Statistical methods: Change in NRQLQ and PSQI total scores from baseline (Visit 1) to end of the study (Visit 2) within the treatment group were measured and analyzed using a t-test for paired differences. *P*-values ≤ 0.05 (2-tailed) were considered significant. A 95% confidence interval for the mean difference was constructed. As a secondary parameter, the individual domains were analyzed.

SUMMARY – CONCLUSIONS

EFFICACY RESULTS: The overall NRQLQ score mean (SD) change from baseline was -1.5 (1.3) (P<0.001), improving from 2.9 (1.2) at baseline to 1.4 (1.2) at end of study. Scores for the domains within the NRQLQ (problems with sleep, symptoms during sleep time, symptoms on waking in the morning, and practical problems) were all statistically significantly better at end of study. Overall PSQI scores improved from a mean (SD) of 9.2 (4.3) at baseline to 6.6 (4.1) at end of study, an overall mean (SD) change of -2.7 (3.6) (P<0.001). Individual domain scores (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction) were all statistically significantly better at end of study.

SAFETY RESULTS: A total of 88 subjects (14%) reported 146 AEs during the study. The most frequently reported AEs were headache (2% of subjects) and sinusitis, upper respiratory infections, nausea, insomnia, bronchitis, and nosebleed (1% of subjects each). All other AEs occurred in less than 0.5% of subjects. 35% (31/88) of subjects had AEs classified as possibly related to study medication, with headache being the AE most frequently considered possibly related to study medication. 2 subjects had serious adverse events (SAEs) (bronchitis, coronary artery disease) during the study. Both SAEs were considered unrelated to study medication. 13 subjects (2%) had AEs that led to discontinuation. Headache, occurring in 4 of these subjects, and nausea, occurring in 2 subjects, were the most common events associated with discontinuation. No subjects died during the study.

Date of the report: 30 April, 2003