These results are supplied for informational purposes only. *Prescribing decisions should be made based on the approved package insert in the country of prescription*			
Sponsor/company:	sanofi-aventis	ClinialTrials.gov Identifier:	NCT00344942
		Study Code:	TRICA_L_00872
Generic drug name:	Triamcinolone acetonide	Date:	29-Dec-2008

Title of the study : a randomised, double-blind, placebo-controlled, French multicentre study to evaluate the efficacy and safety of Nasacort® in chronic nonallergic and noninfectious rhinitis in adults (RhiCNANI)	
Investigator(s) and study center(s) : - Coordinating investigator : Prof. J.M KLOSSEK, Centre Hospitalier Universitaire de Poitiers - Total number of investigators : 100 planned centres ; 68 set up	
Publication(s) : none	
Study Period: - date of first inclusion : 24/04/2006 - date of end of participation of last person included in the study : 22/12/2006	Phase of development :III-b

Objectives:

The primary objective of this study was to demonstrate the superiority of clinical efficacy of 12 weeks' treatment with Nasacort® (220µg/day of triamcinolone acetonide, i.e. two sprays in each nostril once a day) *versus* placebo (two sprays in each nostril once a day) in adult patients presenting with chronic nonallergic and noninfectious rhinitis. Clinical efficacy was evaluated based on the outcome of the symptom global during week 12

The secondary objectives of this study were :

- To evaluate, after 12 weeks' treatment, the improvement in each symptom of chronic nonallergic and noninfectious rhinitis (nasal obstruction, rhinorrhea, disordered sense of smell, sneezing, facial heaviness.
- To evaluate, after 12 weeks' treatment, the improvement in sleep disorders associated with chronic nonallergic noninfectious rhinitis, with the aid of the Epworth® questionnaire on evaluation of drowsiness.
- To evaluate, after 12 weeks' treatment, the improvement in patient quality of life with the SF-36 quality of life questionnaire.
- To demonstrate the superiority of the clinical response to Nasacort® *versus* placebo expressed as the percentage of patients who improved, in the investigator's opinion and the patient's opinion.
- To describe the characteristics of chronic nonallergic noninfectious rhinitis in anterior rhinoscopy and/or endoscopy, with CT scan and nasal cytology.
- To evaluate safety in each treatment group throughout the duration of the study.

Methodology:
A randomised, double-blind, multi-centre, placebo-controlled study to evaluate the efficacy and safety of Nasacort® in Chronic Nonallergic and Noninfectious Rhinitis in adults conducted in France.

Number of patients/subjects :
- number of planned persons : 340
- number of evaluated persons : 77 screened (48 of whom were randomised)

Diagnosis and criteria for inclusion :

Chronic Nonallergic and Noninfectious Rhinitis in adults.

Inclusion criteria

- Patient, male or female, 18 to 65 years of age.
- Patient presenting with Chronic Nonallergic and Noninfectious Rhinitis who can benefit from corticosteroid therapy administered by nasal route.
- Patient with chronic rhinitis of 12 weeks minimum duration, whether or not consecutive, per year.
- Patient with nonallergic rhinitis confirmed by negative phadiatop test.
- Patient with a mean global score for 5 symptoms ≥ 5 (nasal obstruction, rhinorrhea, disorders of sense of smell, sneezing, facial heaviness), or a mean score for the 3 main symptoms (nasal obstruction, rhinorrhea, disorder of sense of smell,) ≥ 5 (mean for 7 days prior to visit V0)
- Patient presenting an inflammation score in anterior rhinoscopy or nasal endoscopy ≥ 4
- Patient who gave his / her written informed consent
- Patient covered by a plan of the social security system or the beneficiary of such a plan

Non-inclusion criteria

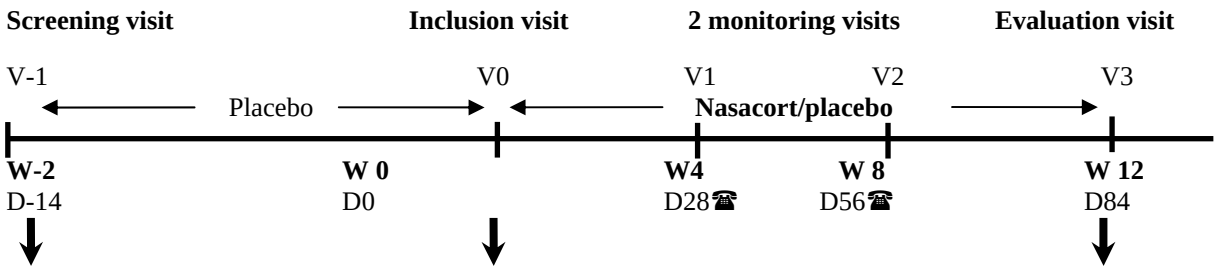
Specific to the study protocol :
- Patient previously included in this study
- Patient participating or who participated in a clinical study within the 30 days prior to V-1 (D-14)
- Patient unable to comply with the study constraints (for example : uncooperative, unable to attend the monitoring visits and probably unable to finish the study)

Specific to the disorder
- Patient presenting with nasal polyps
- Patient presenting with a severe septal deviation which would interfere with insertion of the nasal spray
- Patient presenting with a nasal cavity tumour
- Patient presenting with a sinus infection
- Patient with a history of endonasal surgery
- Patient presenting with a chronic rhinitis of extrinsic origin :
    - Drug-related rhinitis
    - Food-related rhinitis
- Patient presenting with chronic rhinitis of intrinsic origin :
    - Hormonal rhinitis (hormonal, acromegaly, hypothyroidism)
    - Rhinitis in the elderly
    - Positional rhinitis
    - Atrophic rhinitis
    - Primary vasomotor rhinitis

Specific to the patient :
- Patient undergoing a program of intensive sports training
- Patient presenting with : cystic fibrosis, pulmonary mycosis, necrotising vasculitis, immobile cilia syndrome, malabsorption syndrome, sarcoidosis, Wegener's granulomatosis, Rendu Osler angiomatosis
- Patient presenting with known immunosuppression (AIDS or CD4 lymphocyte count < 400 /mm^3, neutropoenia : neutrophils < 1500 /mm^3, haematologic disorder or end-stage cancer, splenectomy, hyposplenism or asplenism), lymphoma
- Patient presenting with a known cardiovascular, neurological or other disorder which is medically important (e.g. tuberculosis) making conduct of the study or interpretation of study results difficult.
- Patient presenting with a disorder whose outcome would be progressively fatal with a life expectancy ≤ 6 months.
- Patient presenting with known renal failure
- Patient presenting with known glaucoma
- Patient presenting with known drug addiction / substance abuse;
- Patient presenting with a mental condition making him unable to understand the nature, objectives and possible consequences of the study.
- Pregnant woman or breast-feeding mother or woman with a positive pregnancy test (plasma β-HCG). Women of child-bearing potential must use an effective method of contraception (intrauterine device, hormonal contraception)
- An adult patient under legal guardianship or a person deprived of his freedom as a result of an administrative or legal decision

Specific to previous and concomitant treatments :
- Ongoing antibiotic therapy (for chronic rhinitis or another disorder)
- Injectable, oral or topical steroids within the 2 months prior to inclusion
- Prescription of treatments unauthorised by the protocol

Specific to the study treatment :
- Patient presenting with hypersensitivity to an ingredient
- Patient presenting with a disorder of haemostasis (epistaxis), ophthalmic infection, and/or oro-bucco-nasal herpetic infection



-Screening criteria
-Information and consent
-SFAR score < 7
-Mean global score for 5 symptoms[4] ≥ 5 or mean score for 3 main symptoms ≥ 5, on day of screening
-Anterior rhinoscopy and/or nasal endoscopy: score ≥ 4
-Phadiatop Prescription
-Prescription of CT scan of sinuses
-Prescription of a Pregnancy Test
-Discontinuation of any ongoing treatment of chronic rhinitis
-Assignment of a screening number
-Faxing of patient contact form
-Distribution of placebo vial
-Distribution of 1st self-evaluation diary[1]

-Inclusion criteria
-Recovery of 1st self-evaluation diary
-Phadiatop result, CT scan of sinuses and pregnancy test
-Mean global score for 5 symptoms[3] ≥ 5 or mean score for 3 main symptoms[3] ≥ 5
- SF-36 and Epworth® Self-questionnaire
-Anterior rhinoscopy and/or nasal endoscopy : score ≥ 4
-Nasal smear
-Randomisation and distribution of treatment
-Distribution of 2nd self-evaluation diary[2]

-Recovery of 2nd self-evaluation diary
-SF-36 and Epworth® self-questionnaire
-Anterior rhinoscopy and/or nasal endoscopy (determination of inflammation score)
-Nasal smear
-Overall evaluation by doctor and patient
-Recovery of treatment diary

[1]-to be returned at V0 (V-1, V0)
[2]-to be returned at V3 (V1, V2, V3))
[3]-collected between D-7 and D-1
[4]-5 symptoms (3 main symptoms in bold letters) : nasal obstruction, rhinorrhea, disorders of sense of smell, sneezing, facial heaviness
☎ telephone contact

Investigational Product:

1/ Nasacort®, *triamcinolone acetonide*, suspension for Nasal Spray, spray bottle of 15 ml (120 sprays) with a dose-dispensing pump and nosepiece dispensing 55 µg triamcinolone acetonide per spray by nasal route, 220 µg per day, i.e. 2 sprays in the morning in each nostril

2/ Placebo, spray bottle, 2 sprays, in the morning, in each nostril
This product has a composition that is identical to that of Nasacort® Nasal Spray but does not contain triamcinolone acetonide

Duration of treatment : 14 weeks (including 2 initial weeks of placebo)

Reference therapy: NA

Criteria for Evaluation :

Efficacy :

1- Primary outcome measure:

Mean global score obtained based on the 10 cm VAS for each of the 5 symptoms
- Nasal obstruction
- Rhinorrhea
- Disorders of sense of smell
- Sneezing
- Facial heaviness

Self-evaluation diaries were to be filled out daily by the patient for 7 days prior to each visit (V0, V1, V2, V3), and each score had to be evaluated before intake of treatment in the morning.

The patient had to return the first self-evaluation diary at V0. The 2nd self-evaluation diary was dispensed at V0 and returned at V3. An outside firm, independent of the sponsor, called the patients 8 days before V0, V1, V2, and V3 to remind them of the date on which they were to start to fill out this diary.

2 – Secondary outcome measures :

- Score for each nasal symptom obtained with the 10 cm VAS
  - Nasal obstruction
  - Rhinorrhea
  - Disorders of sense of smell
  - Sneezing
  - Facial heaviness
- Evaluation of outcome of quality of life criteria with an SF-36 quality of life global
- Evaluation of daytime sleepiness using the Epworth® Sleepiness Scale (ESS)
- Clinical response : in the investigator's opinion and in the patient's opinion
- Descriptive data of anterior rhinoscopy and/or nasal endoscopy, CT scans and nasal cytology
- Safety data : collection of adverse events throughout the duration of treatment

Statistical methods:

Evaluated Population :
The ITTm population (modified ITT) is comprised of randomised patients who took at least one dose of allocated study treatment
The Per-Protocol population is a subset of the ITTm population, excluding patients who had at least one major protocol violation.

The safety population is comprised of all patients who signed an informed consent and who took at least one dose of placebo treatment.

The primary outcome measure will be analysed on the ITTm population as well as the secondary outcome measures and safety analysed on all patients who received at least one dose of treatment.

Analytical methods

Primary outcome measures:

Comparison of treatment groups on the mean score obtained based on the VAS for the 5 symptoms during week 12 (V3), performed with analysis of covariance adjusted to the value obtained at inclusion (V0) and to the centre. An additional analysis adjusted to the centre and with repeated measures was to determine if a difference existed between the treatment groups in terms of outcome of mean global scores during the study.

Furthermore, the robustness of the primary analysis was to be checked by comparing the responders, defined as those patients having an improvement of at least 50% in the mean global score at V3 compared to baseline (V0), with Fisher's exact test. This analysis will be adjusted by centre if a centre effect is observed in the primary analysis.
The primary analysis was on the ITTm; an additional analysis was to be performed on the per-protocol population as well.

Two-sided tests performed with a level α equal to 1 %.

Secondary outcome measures :

VAS by symptom at week 12 (V3), the Quality of Life score (SF-36) and Epworth® Sleepiness Scale scores were to be analysed with ITTm by analysis of covariance adjusted to the value at inclusion and to the centre.

The clinical response in terms of percent of patient improved at V3, in the investigator's opinion and the patient's opinion, were to be compared between the two groups with Fisher's exact test.

For exploratory and descriptive analysis, nasal cytology at inclusion and at the end of treatment was to be analysed and results at V3 was to be cross-compared with cytological results at V0. Furthermore, the correlation between the cytological results and the clinical results was to be analysed descriptively.

Safety was to be analysed descriptively.

The inflammation score was to be described at V-1, V0 and V3.

Decision-making procedure concerning efficacy of treatment : If analysis of the primary outcome measure is significant, the results concerning all secondary outcome measures will be considered as additional illustrations. If not, the secondary outcome measures will be classified and the 3 following symptoms as well as the Epworth Sleepiness Scale scores were considered as having priority : nasal obstruction, rhinorrhea, disorders of sense of smell. Results of these 4 parameters were considered significant only if :

- at least one of the 4 p-values associated with the tests of treatment effect is less than or equal to 0.0025.

or

- at least two of the 4 p-values are less than or equal to 0.0050

or

- at least three of the 4 p-values are less than or equal to 0.0075

or

- the 4 p-values are less than or equal to 0.0100.

- safety : clinical safety was evaluated systematically by the investigator at the different visits and at each phone call by a non-directed questionnaire. The type, frequency and severity of adverse events were recorded in the case report forms.

  If the investigator considered that it was necessary to report an adverse event occurring in a patient after the observation period, he/she had to contact the sponsor to determine how this adverse event had to be documented and reported.

Statistical analysis:

Since the study was terminated in December 2006 before the end of inclusions due to difficulty in recruitment of this type of patient in general medicine, only a descriptive analysis of available data has been performed.

All parameters for which information is given have been described at V-1 and V0 and no tests of comparison have been performed.

- patient characteristics
- mean global VAS score for 5 symptoms (nasal obstruction, rhinorrhea, disorders of sense of smell, sneezing, facial heaviness) or mean VAS global score for the 3 main symptoms, score of each nasal symptom, nasal cytologies, inflammation score with rhinoscopy/endoscopy at V-1 and V0, phadiatop and CT scans of sinuses at V0.
- safety parameters measured during the P1 period (wiith placebo) and those which occurred during the P2 period of treatment after randomisation.
- No specific treatment of missing values.

Summary:

- This is an abridged report. It was planned to include 340 patients with nonallergic non-infectious rhinitis over a 15 month period. In the present study as a result of major difficulties in recruitment related to rigorousness for some pre-screening and screening criteria, 77 patients were recruited, 48 of whom were randomised over an 8 month period. It was decided to terminate the study, thus initially planned evaluations of efficacy were not performed because not relevant.

- Patient status :

Total Population *	N(%)	77 (100.0)
Screened patients who never took placebo (SNP)	N(%)	3 (3.9)
Safety population **	N(%)	74 (96.1)
Screened patients who took placebo during the P1 period but were not randomised (SPNR)	N(%)	26 (33.8)
Screened and randomised patients but not treated during P1 (SPRNT)	N(%)	0 (0.0)
Screened,randomised patients who took at least one dose of treatment during period P2 (SPRT)	N(%)	48 (62.3)
Nasacort® group of patients	N(%)	25 (32.5)
Placebo group of patients	N(%)	23 (29.9)

* The total population consists of all patients included after informed consent was obtained (the combination of the four subgroups : SNP + SPNR + SPRNT + SPRT).
** The safety population is comprised of all patients included after informed consent was obtained and who took at least one dose of treatment (the combination of the three subgroups : SPNR + SPRNT + SPRT).

- Demographic characteristics and description of population :

A/ Demographic characteristics of the population

			Patients screened during P1	Patients treated during P2		
			Patients screened who took placebo but were not randomised (SPNR)	Nasacort®	Placebo	Total patients treated
Total number of patients		N	26	25	23	48
Gender		N	26	25	23	48
		N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Male	N(%)	9 (34.6)	7 (28.0)	10 (43.5)	17 (35.4)
	Female	N(%)	17 (65.4)	18 (72.0)	13 (56.5)	31 (64.6)
Age (years)		N	26	25	23	48
		N missing data	0	0	0	0
		Mean (s.d.)	37.2 (10.3)	38.8 (11.3)	46.8 (14.2)	42.6 (13.2)
		Median	36.0	38.0	48.0	41.5
		Min - Max	20 ; 61	18 ; 62	19 ; 67	18 ; 67
Smoker		N	26	25	23	48
		N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	No	N(%)	22 (84.6)	21 (84.0)	20 (87.0)	41 (85.4)
	Yes	N(%)	4 (15.4)	4 (16.0)	3 (13.0)	7 (14.6)
Number of packs / year		N	3	3	2	5
		N missing data	1	1	1	2
		Mean (s.d.)	7.7 (2.5)	32.7 (14.2)	15.0 (17.0)	25.6 (16.3)
		Median	8.0	30.0	15.0	27.0
		Min - Max	5 ; 10	20 ; 48	3 ; 27	3 ; 48
Former Smoker		N	26	25	23	48
		N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	No	N(%)	20 (76.9)	24 (96.0)	19 (82.6)	43 (89.6)
	Yes	N(%)	6 (23.1)	1 (4.0)	4 (17.4)	5 (10.4)
Pregnancy test		N	17	18	13	31
		N(%) missing data	4 (23.5)	3 (16.7)	6 (46.2)	9 (29.0)
	Negative	N(%)	13 (76.5)	15 (83.3)	7 (53.8)	22 (71.0)
	Positive	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

B/ Description of population - History of the present illness and previous disorders

			Patients screened during P1	Patients treated during P2		
			Patients screened Who took placebo But were not randomised (SPNR)	Nasacort®	Placebo	Total patients treated
Total number of patients		N	26	25	23	48
Duration of chronic rhinitis (months)		N	26	25	22	47
		N missing data	0	0	1	1
		Median	86.5	84.0	105.0	89.0
		Mean (s.d.)	94.8 (75.5)	138.2 (100.4)	157.7 (164.1)	147.3 (132.
		Min - Max	3 ; 313	27 ; 436	6 ; 675	6 ; 675
Total number of patients With at least one previous disorder And/or a concomitant disorder		N	26	25	23	48
		N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	No	N(%)	15 (57.7)	12 (48.0)	11 (47.8)	23 (47.9)
	Yes	N(%)	11 (42.3)	13 (52.0)	12 (52.2)	25 (52.1)

B/ Description of population - Mean nasal symptom score

		Patients screened during P1	Patients treated during P2		
		Patients screened who took placebo but were not randomised (SPNR)	Nasacort®	Placebo	Total patients treated
Total number of patients	N	26	25	23	48
Mean global score of 5 nasal symptoms (VAS) at V-1	N	26	25	23	48
	N missing data	0	0	0	0
	Mean (s.d.)	55.3 (15.1)	57.4 (12.1)	56.5 (15.5)	57.0 (13.7)
	Median	55.5	53.0	56.0	56.0
	Min - Max	6 ; 81	33 ; 80	21 ; 86	21 ; 86
Mean global score of 5 nasal symptoms (VAS) at V0	N	23	25	23	48
	N missing data	3	0	0	0
	Mean (s.d.)	35.0 (21.5)	50.1 (15.3)	52.2 (16.7)	51.1 (15.9)
	Median	29.0	52.0	53.0	52.5
	Min - Max	6 ; 76	2 ; 74	12 ; 75	2 ; 75
Mean global score of 3 main nasal symptoms* (VAS) at V-1	N	26	25	23	48
	N missing data	0	0	0	0
	Mean (s.d.)	58.1 (15.6)	62.3 (13.0)	60.5 (16.7)	61.4 (14.8)
	Median	58.0	61.0	60.0	60.5
	Min - Max	6 ; 87	34 ; 85	27 ; 92	27 ; 92
Mean global score of 3 main nasal symptoms* (VAS) at V0	N	23	25	23	48
	N missing data	3	0	0	0
	Mean (s.d.)	37.2 (22.0)	58.0 (16.4)	56.3 (16.8)	57.2 (16.5)
	Median	35.0	62.0	59.0	59.0
	Min - Max	8 ; 79	2 ; 84	17 ; 85	2 ; 85

B/ Description of population - Mean nasal symptom score

		Patients screened during P1	Patients treated during P2		
		Patients screened who took placebo But were not randomised (SPNR)	Nasacort®	Placebo	Total patients treated
Total number of patients	N	26	25	23	48
Nasal obstruction score (VAS) at V-1	N	26	25	23	48
	N missing data	0	0	0	0
	Mean (s.d.)	77.1 (12.7)	79.2 (19.8)	78.5 (14.2)	78.9 (17.2)
	Median	75.0	80.0	78.0	79.0
	Min - Max	51 ; 100	25 ; 100	46 ; 100	25 ; 100
Nasal obstruction score (VAS) at V0	N	23	25	23	48
	N missing data	3	0	0	0
	Mean (s.d.)	51.7 (28.2)	66.9 (21.1)	68.7 (18.6)	67.8 (19.7)
	Median	49.3	72.4	74.0	73.2
	Min - Max	10 ; 100	7 ; 93	26 ; 97	7 ; 97
Rhinorrhea score (VAS) at V-1	N	26	25	23	48
	N missing data	0	0	0	0
	Mean (s.d.)	62.3 (26.5)	62.6 (27.7)	64.6 (29.4)	63.5 (28.2)
	Median	73.0	69.0	70.0	69.5
	Min - Max	10 ; 98	2 ; 97	5 ; 100	2 ; 100
Rhinorrhea score (VAS) at V0	N	23	25	23	48
	N missing data	3	0	0	0
	Mean (s.d.)	33.7 (24.3)	57.7 (25.6)	58.2 (29.7)	57.9 (27.3)
	Median	24.9	64.5	69.4	65.7
	Min - Max	4 ; 82	0 ; 93	5 ; 88	0 ; 93
Disorders of sense of smell score(VAS) at V-1	N	26	25	23	48
	N missing data	0	0	0	0
	Mean (s.d.)	42.0 (32.5)	45.3 (31.1)	38.8 (25.3)	42.2 (28.4)
	Median	36.0	50.0	40.0	44.5
	Min - Max	0 ; 95	0 ; 98	0 ; 82	0 ; 98
Disorders of sense of Smell score (VAS) at V0	N	23	25	23	48
	N missing data	3	0	0	0
	Mean (s.d.)	29.6 (33.2)	52.1 (30.0)	42.2 (25.5)	47.3 (28.1)
	Median	16.3	57.0	46.7	53.9
	Min - Max	0 ; 100	0 ; 96	0 ; 87	0 ; 96

B/ Description of population - Mean score by nasal symptom (continued)

		Patients screened during P1	Patients treated during P2		
		Patients screened who took placebo but were not randomised (SPNR)	Nasacort®	Placebo	Total patients treated
Total number of patients	N	26	25	23	48
Sneezing score (VAS) at V-1	N	26	25	23	48
	N missing data	0	0	0	0
	Mean (s.d.)	48.2 (27.7)	43.2 (27.9)	50.1 (28.2)	46.5 (28.0)
	Median	52.5	46.0	56.0	49.0
	Min - Max	2 ; 88	3 ; 99	3 ; 100	3 ; 100
Sneezing score (VAS) at V0	N	23	25	23	48
	N missing data	3	0	0	0
	Mean (s.d.)	23.3 (24.0)	31.7 (24.6)	45.4 (25.0)	38.3 (25.4)
	Median	13.7	24.1	45.1	33.8
	Min - Max	0 ; 97	1 ; 80	2 ; 86	1 ; 86
Facial heaviness score (VAS) at V-1	N	26	25	23	48
	N missing data	0	0	0	0
	Mean (s.d.)	58.8 (28.0)	57.8 (32.7)	50.7 (34.2)	54.4 (33.2)
	Median	59.0	62.0	61.0	61.5
	Min - Max	0 ; 98	0 ; 100	0 ; 99	0 ; 100
Facial heaviness score (VAS) at V0	N	23	25	23	48
	N missing data	3	0	0	0
	Mean (s.d.)	41.8 (33.7)	46.5 (30.1)	46.5 (29.0)	46.5 (29.3)
	Median	39.9	43.0	52.9	47.9
	Min - Max	0 ; 100	0 ; 97	0 ; 99	0 ; 99

B/ Description of the population - Description of rhinoscopy/endoscopy at V-1

		Patients screened during P1	Patients treated during P2		
		Patients screened who took placebo but were not randomised (SPNR)	Nasacort®	Placebo	Total patients treated
Total number of patients	N	26	25	23	48
Inflammation total score	N	26	25	22	47
	N missing data	0	0	1	1
	Mean (s.d.)	7.8 (2.4)	8.5 (2.3)	8.4 (1.6)	8.5 (2.0)
	Median	8.0	8.0	8.0	8.0
	Min - Max	2 ; 12	4 ; 12	6 ; 12	4 ; 12
Presence of secretion	N	26	25	23	48
	N(%) missing data	0 (0.0)	0 (0.0)	1 (4.3)	1 (2.1)
Yes with one-sided test	N(%)	1 (3.8)	0 (0.0)	1 (4.3)	1 (2.1)
Yes with two-sided test	N(%)	22 (84.6)	25 (100.0)	20 (87.0)	45 (93.8)
No	N(%)	3 (11.5)	0 (0.0)	1 (4.3)	1 (2.1)
Presence of filamentous secretion	N	26	25	23	48
	N(%) missing data	2 (7.7)	0 (0.0)	2 (8.7)	2 (4.2)
Yes with one-sided test	N(%)	2 (7.7)	0 (0.0)	1 (4.3)	1 (2.1)
Yes with two-sided test	N(%)	16 (61.5)	23 (92.0)	17 (73.9)	40 (83.3)
No	N(%)	6 (23.1)	2 (8.0)	3 (13.0)	5 (10.4)
Quantity of filamentous secretion with one-sided test	N	2	0 (0.0)	1	1
	N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mild	N(%)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)
Moderate	N(%)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
Severe	N(%)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)
Filamentous secretion with two-sided test	N	16	23	17	40
	N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mild	N(%)	4 (25.0)	3 (13.0)	1 (5.9)	4 (10.0)
Moderate	N(%)	12 (75.0)	16 (69.6)	11 (64.7)	27 (67.5)
Severe	N(%)	0 (0.0)	4 (17.4)	5 (29.4)	9 (22.5)
Presence of thick secretion	N	26	25	23	48
	N(%) missing data	2 (7.7)	0 (0.0)	2 (8.7)	2 (4.2)
Yes with one-sided test	N(%)	1 (3.8)	1 (4.0)	0 (0.0)	1 (2.1)
Yes with two-sided test	N(%)	5 (19.2)	2 (8.0)	3 (13.0)	5 (10.4)
No	N(%)	18 (69.2)	22 (88.0)	18 (78.3)	40 (83.3)

B/ Description of population - Description of rhinoscopy/endoscopy at V-1 (continued)

			Patients screened during P1	Patients treated during P2		
			Patients screened who took placebo but were not randomised (SPNR)	Nasacort®	Placebo	Total patients treated
Quantity of thick secretion with one-sided test		N	1	1	0 (0.0)	1
		N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Mild	N(%)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Moderate	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Severe	N(%)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Quantity of thick secretion with two-sided test		N	5	2	3	5
		N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Mild	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Moderate	N(%)	2 (40.0)	1 (50.0)	3 (100.0)	4 (80.0)
	Severe	N(%)	3 (60.0)	1 (50.0)	0 (0.0)	1 (20.0)
Red mucosa (congestive)		N	26	25	23	48
		N(%) missing data	0 (0.0)	0 (0.0)	1 (4.3)	1 (2.1)
	Yes with one-sided test	N(%)	2 (7.7)	0 (0.0)	1 (4.3)	1 (2.1)
	Yes with two-sided test	N(%)	21 (80.8)	18 (72.0)	15 (65.2)	33 (68.8)
	No	N(%)	3 (11.5)	7 (28.0)	6 (26.1)	13 (27.1)
Intensity of red mucosa (congestive) with one-sided test		N	2	0 (0.0)	1	1
		N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Mild	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Moderate	N(%)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Severe	N(%)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
Intensity of red mucosa (congestive) with two-sided test		N	21	18	15	33
		N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Mild	N(%)	2 (9.5)	5 (27.8)	0 (0.0)	5 (15.2)
	Moderate	N(%)	12 (57.1)	6 (33.3)	9 (60.0)	15 (45.5)
	Severe	N(%)	7 (33.3)	7 (38.9)	6 (40.0)	13 (39.4)
Pale mucosa (oedematous)		N	26	25	23	48
		N(%) missing data	0 (0.0)	0 (0.0)	1 (4.3)	1 (2.1)
	Yes with one-sided test	N(%)	2 (7.7)	0 (0.0)	1 (4.3)	1 (2.1)
	Yes with two-seded test	N(%)	3 (11.5)	7 (28.0)	6 (26.1)	13 (27.1)
	No	N(%)	21 (80.8)	18 (72.0)	15 (65.2)	33 (68.8)

B/ Description of population - Description of rhinoscopy/endoscopy at V-1 (continued)

			Patients screened during P1	Patients treated during P2		
			Patients screened who took placebo but were not randomised (SPNR)	Nasacort®	Placebo	Total patients treated
Intensity of pale mucosa (oedematous) with one-sided test		N	2	0 (0.0)	1	1
		N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Mild	N(%)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Moderate	N(%)	1 (50.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Severe	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intensity of pale mucosa (oedematous) with two-sided test		N	3	7	6	13
		N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Mild	N(%)	1 (33.3)	1 (14.3)	0 (0.0)	1 (7.7)
	Moderate	N(%)	2 (66.7)	4 (57.1)	5 (83.3)	9 (69.2)
	Severe	N(%)	0 (0.0)	2 (28.6)	1 (16.7)	3 (23.1)

B/ Description of population - Description of rhinoscopy/endoscopy at V0

		Patients screened during P1	Patients treated during P2		
		Patients screened who took placebo but were not randomised (SPNR)	Nasacort®	Placebo	Total patients treated
Total number of patients	N	26	25	23	48
Inflammation total score	N	18	24	22	46
	N missing data	8	1	1	2
	Mean (s.d.)	6.7 (2.8)	8.8 (2.3)	8.4 (2.5)	8.6 (2.4)
	Median	6.0	8.0	8.0	8.0
	Min - Max	2 ; 12	6 ; 14	1 ; 13	1 ; 14
Presence of secretion	N	26	25	23	48
	N(%) missing data	8 (30.8)	1 (4.0)	1 (4.3)	2 (4.2)
Yes with one-sided test	N(%)	0 (0.0)	0 (0.0)	1 (4.3)	1 (2.1)
Yes with two-sided test	N(%)	16 (61.5)	24 (96.0)	21 (91.3)	45 (93.8)
No	N(%)	2 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)
Presence of filamentous secretion	N	26	25	23	48
	N(%) missing data	10 (38.5)	1 (4.0)	1 (4.3)	2 (4.2)
Yes with one-sided test	N(%)	1 (3.8)	2 (8.0)	2 (8.7)	4 (8.3)
Yes with two-sided test	N(%)	12 (46.2)	18 (72.0)	17 (73.9)	35 (72.9)
No	N(%)	3 (11.5)	4 (16.0)	3 (13.0)	7 (14.6)
Quantity of filamentous secretion with one-sided test	N	1	2	2	4
	N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mild	N(%)	1 (100.0)	0 (0.0)	1 (50.0)	1 (25.0)
Moderate	N(%)	0 (0.0)	2 (100.0)	1 (50.0)	3 (75.0)
Severe	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Quantity of filamentous secretion with two-sided test	N	12	18	17	35
	N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mild	N(%)	5 (41.7)	1 (5.6)	2 (11.8)	3 (8.6)
Moderate	N(%)	7 (58.3)	13 (72.2)	12 (70.6)	25 (71.4)
Severe	N(%)	0 (0.0)	4 (22.2)	3 (17.6)	7 (20.0)
Presence of thick secereticn	N	26	25	23	48
	N(%) missing data	10 (38.5)	1 (4.0)	2 (8.7)	3 (6.3)
Yes with one-sided test	N(%)	0 (0.0)	2 (8.0)	1 (4.3)	3 (6.3)
Yes with two-sided test	N(%)	3 (11.5)	4 (16.0)	3 (13.0)	7 (14.6)
No	N(%)	13 (50.0)	18 (72.0)	17 (73.9)	35 (72.9)

B/ Description of population - Description of rhinoscopy/endoscopy at V0 (continued)

		Patients screened during P1	Patients treated during P2		
		Patients screened who took placebo but were not randomised (SPNR)	Nasacort®	Placebo	Total patients treated
Total number of patients	N	26	25	23	48
Quantity of thick secretion with one-sided test	N	0	2	1	3
	N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mild	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Moderate	N(%)	0 (0.0)	2 (100.0)	1 (100.0)	3 (100.0)
Severe	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Quantity of thick secretion with two-sided test	N	3	4	3	7
	N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mild	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Moderate	N(%)	2 (66.7)	3 (75.0)	3 (100.0)	6 (85.7)
Severe	N(%)	1 (33.3)	1 (25.0)	0 (0.0)	1 (14.3)
Red mucosa (congestive)	N	26	25	23	48
	N(%) missing data	8 (30.8)	1 (4.0)	2 (8.7)	3 (6.3)
Yes with one-sided test	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Yes with two-sided test	N(%)	17 (65.4)	18 (72.0)	15 (65.2)	33 (68.8)
No	N(%)	1 (3.8)	6 (24.0)	6 (26.1)	12 (25.0)
Intensity of red mucosa (congestive) with one-sided test	N	0	0	0	0
	N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mild	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Moderate	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Severe	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intensity of red mucosa (congestive) with two-sided test	N	17	18	15	33
	N(%) missing data	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)
Mild	N(%)	5 (29.4)	1 (5.6)	0 (0.0)	1 (3.0)
Moderate	N(%)	7 (41.2)	10 (55.6)	8 (53.3)	18 (54.5)
Severe	N(%)	4 (23.5)	7 (38.9)	7 (46.7)	14 (42.4)

B/ Description of population - Description of rhinoscopy/endoscopy at V0 (continued)

			Patients screened during P1	Patients treated during P2		
			Patients screened who took placebo but were not randomised (SPNR)	Nasacort®	Placebo	Total patients treated
Total number of patients		N	26	25	23	48
Pale mucosa (oedematous)		N	26	25	23	48
		N(%) missing data	8 (30.8)	1 (4.0)	2 (8.7)	3 (6.3)
	Yes with one-sided test	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Yes with two-sided test	N(%)	1 (3.8)	6 (24.0)	6 (26.1)	12 (25.0)
	No	N(%)	17 (65.4)	18 (72.0)	15 (65.2)	33 (68.8)
Intensity of pale mucosa (oedematous) with one-sided test		N	0	0	0	0
		N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Mild	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Moderate	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Severe	N(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intensity of pale mucosa (oedematous) with two-sided		N	1	6	6	12
		N(%) missing data	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Mild	N(%)	0 (0.0)	1 (16.7)	1 (16.7)	2 (16.7)
	Moderate	N(%)	0 (0.0)	3 (50.0)	3 (50.0)	6 (50.0)
	Severe	N(%)	1 (100.0)	2 (33.3)	2 (33.3)	4 (33.3)

- Results of evaluation of safety :

	Adverse events during period P1 N (%)	All adverse events during period P1 considered as related N (%)
Total number of patients	26	26
Total number of patients with at least one TEAE*	3 (11.5)	0 (0.0)
Organ system :		
Gastrointestinal disorders	1 (3.8)	0 (0.0)
Epigastric pain	1 (3.8)	0 (0.0)
Infections and infestations	2 (7.7)	0 (0.0)
Bronchitis	1 (3.8)	0 (0.0)
Sinusitis	1 (3.8)	0 (0.0)
Infectious complication	1 (3.8)	0 (0.0)
Tonsillitis	1 (3.8)	0 (0.0)

*TEAE = treatment emergent adverse event

	Adverse events during period P2 Treated patients		All adverse events during period P2 considered as related Treated patients	
	Nasacort® N (%)	Placebo N (%)	Nasacort® N (%)	Placebo N (%)
Total number of patients	25	23	25	23
Total number of patients with at least one TEAE *	3 (12.0)	5 (21.7)	1 (4.0)	1 (4.3)
Organ system :				
Gastrointestinal disorders	0 (0.0)	1 (4.3)	0 (0.0)	0 (0.0)
Dyspepsia	0 (0.0)	1 (4.3)	0 (0.0)	0 (0.0)
Infections and infestations	1 (4.0)	3 (13.0)	0 (0.0)	0 (0.0)
Bronchitis	0 (0.0)	2 (8.7)	0 (0.0)	0 (0.0)
Otitis media	0 (0.0)	1 (4.3)	0 (0.0)	0 (0.0)
Sinusitis	1 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pulmonary infectious complications	0 (0.0)	1 (4.3)	0 (0.0)	0 (0.0)
Nervous system disorders	1 (4.0)	2 (8.7)	0 (0.0)	0 (0.0)
Headache	1 (4.0)	1 (4.3)	0 (0.0)	0 (0.0)
Migraine	0 (0.0)	1 (4.3)	0 (0.0)	0 (0.0)
Psychiatric disorders	0 (0.0)	1 (4.3)	0 (0.0)	1 (4.3)
Insomnia	0 (0.0)	1 (4.3)	0 (0.0)	1 (4.3)
Respiratory thoracic and mediastinal disorders	1 (4.0)	0 (0.0)	1 (4.0)	0 (0.0)
Nasal discomfort	1 (4.0)	0 (0.0)	1 (4.0)	0 (0.0)

*TEAE = Treatment emergent adverse event

No serious adverse event or death was reported. The safety profile on Nasacort® is the usual profile

Date of report : October 2007