

The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

Study No.: FFU108556
Title: Study FFU108556, A Patient Preference Evaluation Study of Fluticasone Furoate Nasal Spray and Fluticasone Propionate Aqueous Nasal Spray in Subjects with Allergic Rhinitis
Rationale: The purpose of this single-dose preference evaluation study was to provide data on subject preference of fluticasone furoate (FF) nasal spray as compared to generic fluticasone propionate (FP) nasal spray in the treatment of allergic rhinitis (AR), based on sensory attributes.
Phase: IIIb
Study Period: Initiation 01 December 2006 – Completion 04 December 2006
Study Design: This was a multicenter, randomised, double-blind, single-dose crossover study completed in a single clinic visit. Following screening, subjects were administered a single dose of each study medication. Following each treatment, an immediate and a delayed (2 minutes following treatment) subject-rated sensory attributes questionnaire was completed. At the end of the crossover dosing and following completion of the attributes questionnaires, the overall subject preference for FF or FP nasal spray was evaluated in a third questionnaire.
Centres: This was a multicentre study conducted at 12 investigator sites in the United States.
Indication: Allergic rhinitis (AR)
Treatment: Using metering, atomising nasal spray pumps, FF was delivered as an aqueous suspension containing 0.05% w/w of micronised FF, with each actuation providing approximately 27.5 mcg of FF. Generic FP was delivered as an aqueous suspension of microfine FP, with each actuation delivering 50 mcg in 100 mg of formulation. Subjects received total doses of 110 mcg FF and 200 mcg FP in a crossover manner.
Objectives: The objective of this study was to evaluate and compare subject preference, based on selected sensory attributes, for FF and FP nasal sprays in the treatment of AR following single-dose administration.
Primary Outcome/Efficacy Variable: Overall subject preference for FF and FP nasal sprays based on selected product attributes at the end of the crossover dosing.
Secondary Outcome/Efficacy Variable(s): Subject preference for individual sensory attributes and subject ratings of individual attributes of FF and FP nasal sprays.
Statistical Methods: A sample size of 125 provides 93% power to show an overall preference for one treatment over the other of 65% (one-sample chi-square test). All hypotheses were two-tailed with 95% confidence intervals and significance level set at $\alpha=0.05$. Type I errors were controlled by a gatekeeper strategy which prohibited statistical inferences about individual attribute preferences or ratings unless the overall preference was statistically significant. No interim analyses were carried out, nor was hypothesis testing of the baseline characteristics undertaken. The Intent to treat (ITT) population consisted of all subjects who were randomised to be treated with the study drug, and formed the basis for all summaries of safety, background, and demographic data. The Per Protocol (PP) population included all subjects who completed both treatment periods; analyses of all preference and attribute ratings results were based on this group. Deviation from the protocol, as determined prior to the unblinding of treatment assignments, resulted in exclusion from the PP population. Overall subject preference for FP or FF was analysed using a Cochran-Mantel-Haenszel test, adjusted for investigator. Homogeneity among investigative sites with respect to treatment preference was assessed using Breslow-Day tests. Subject preference for and ratings of individual attributes were each analysed using analysis of variance tests with main effects for treatment, treatment sequence, period, investigator, and subject within sequence. Attributes rated immediately (immediate questionnaire) and 2 minutes (delayed questionnaire) after each study drug administration were analysed separately. Post-randomisation AEs and drug-related AEs were coded and grouped by system organ class (SOC) and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA). The number and percentage of subjects with AEs that started during the treatment period and led to withdrawal from the study were tabulated and listed by subject.
Study Population: Prior to study enrolment, male and female subjects were screened and deemed eligible to partake in the study if they provided a signed and dated informed consent, were ≥ 18 years of age and had a diagnosis of AR (positive skin test to perennial and/or seasonal allergens within the last 12 months prior to the study or during screening). Females of childbearing potential were eligible if a urine pregnancy test proved negative and if they were committed to birth control. Key exclusion criteria included concomitant medical conditions, use of intranasal corticosteroids and medications within 4 weeks prior to study participation, and allergy/tolerance to corticosteroids, antihistamines or any excipients in FF or FP.
Total

Planned, N	125			
Randomised, N	127			
Completed, n (%) ^a	127 (100%)			
Total Number Subjects Withdrawn, N (%)	0 (0%)			
Withdrawn due to Adverse Events n (%)	0 (0%)			
Withdrawn due to Lack of Efficacy n (%)	Not applicable			
Withdrawn for other reasons n (%)	0 (0%)			
Following completion, 6 subjects (5%) were excluded from the PP population due to protocol deviation, resulting in a PP population of 121 subjects (95%).				
Demographics				
	Total			
N (ITT)	127			
Females: Males	45:82			
Mean Age, years (SD)	39.7 (14.05)			
White, n (%)	101 (80%)			
Primary Outcome Variables: Overall subject preference for nasal spray				
	FF / FP (N=60)	FP / FF (N=61)	Total (N=121)	p-value
Overall product preference				
n	59	61	120	0.003
FF	38 (64%)	34 (56%)	72 (60%)	
FP	19 (32%)	20 (33%)	39 (33%)	
No preference	2 (3%)	7 (11%)	9 (8%)	
Scent/odour				
n	59	61	120	<0.001
FF	41 (69%)	36 (59%)	77 (64%)	
FP	14 (24%)	21 (34%)	35 (29%)	
No preference	4 (7%)	4 (7%)	8 (7%)	

Continued

Primary Outcome Variables: Overall subject preference for nasal spray <i>continued</i>				
	FF / FP	FP / FF	Total	p value
Immediate taste				
n	59	61	120	<0.001
FF	32 (54%)	24 (39%)	56 (47%)	
FP	11 (19%)	14 (23%)	25 (21%)	
No preference	16 (27%)	23 (38%)	39 (33%)	
After-taste				
n	59	61	120	0.002
FF	30 (51%)	23 (38%)	53 (44%)	
FP	12 (20%)	14 (23%)	26 (22%)	
No preference	17 (29%)	24 (39%)	41 (34%)	
Less drip down throat				
n	59	61	120	0.037
FF	29 (49%)	23 (38%)	52 (43%)	
FP	16 (27%)	16 (26%)	32 (27%)	
No preference	14 (24%)	22 (36%)	36 (30%)	
Less run out of nose				
n	59	61	120	<0.001
FF	32 (54%)	27 (44%)	59 (49%)	
FP	11 (19%)	12 (20%)	23 (19%)	
No preference	16 (27%)	22 (36%)	38 (32%)	
More soothing				
n	59	61	120	0.408
FF	26 (44%)	19 (31%)	45 (38%)	
FP	15 (25%)	23 (38%)	38 (32%)	
No preference	18 (31%)	19 (31%)	37 (31%)	
Less irritating				
n	59	61	120	0.070
FF	21 (36%)	20 (33%)	41 (34%)	
FP	9 (15%)	17 (28%)	26 (22%)	
No preference	29 (49%)	24 (39%)	53 (44%)	
Urge to sneeze				
n	59	61	120	0.587
FF	14 (24%)	11 (18%)	25 (21%)	
FP	7 (12%)	14 (23%)	21 (18%)	
No preference	38 (64%)	36 (59%)	74 (62%)	
Secondary Outcome Variable(s): Subject ratings of individual sensory attributes, immediate and delayed attributes questionnaires				
	Immediate attributes questionnaire		Delayed attributes questionnaire	
	FF	FP	FF	FP
Did product have a scent/odour?				
n	121	120	121	121
None	62 (51%)	12 (10%)	71 (59%)	16 (13%)
Very mild	27 (22%)	22 (18%)	21 (17%)	19 (32%)
Mild	19 (16%)	35 (29%)	16 (13%)	29 (24%)
Neither mild nor strong	2 (2%)	7 (6%)	4 (3%)	4 (3%)
Slightly strong	6 (5%)	20 (17%)	6 (5%)	20 (17%)
Moderately strong	4 (3%)	19 (16%)	2 (2%)	10 (8%)
Very strong	1 (<1%)	5 (4%)	1 (<1%)	3 (2%)

Continued

Secondary Outcome Variable(s): Subject ratings of individual sensory attributes, immediate and delayed attributes questionnaires, <i>continued</i>				
	Immediate attributes questionnaire		Delayed attributes questionnaire	
	FF	FP	FF	FP
How satisfied with scent/odour?				
n	61	109	53	106
Very satisfied	11 (18%)	16 (15%)	14 (26%)	19 (18%)
Moderately satisfied	12 (20%)	20 (18%)	11 (21%)	21 (20%)
Somewhat satisfied	13 (21%)	25 (23%)	12 (23%)	20 (19%)
Neither satisfied nor dissatisfied	16 (26%)	17 (16%)	10 (19%)	22 (21%)
Somewhat dissatisfied	6 (10%)	23 (21%)	5 (9%)	16 (15%)
Moderately dissatisfied	1 (2%)	5 (5%)	0	6 (6%)
Very dissatisfied	2 (3%)	3 (3%)	1 (2%)	2 (2%)
How satisfied not to have scent/odour				
n	63	14	74	16
Very satisfied	46 (73%)	10 (71%)	56 (76%)	14 (88%)
Moderately satisfied	7 (11%)	2 (14%)	2 (3%)	1 (6%)
Somewhat satisfied	1 (2%)	0	4 (5%)	0
Neither satisfied nor dissatisfied	6 (10%)	1 (7%)	8 (11%)	1 (6%)
Somewhat dissatisfied	2 (3%)	0	3 (4%)	0
Moderately dissatisfied	0	0	0	0
Very dissatisfied	1 (2%)	1 (7%)	1 (1%)	0
Did product have an immediate taste?				
n	121	121		
No taste	98 (81%)	69 (57%)		
Very mild taste	10 (8%)	25 (21%)		
Mild taste	7 (6%)	13 (11%)		
Neither mild nor strong taste	2 (2%)	6 (5%)		
Slightly strong taste	3 (2%)	6 (5%)		
Moderately strong taste	1 (<1%)	2 (2%)		
Very strong taste	0	0		
How satisfied with immediate taste?				
n	33	54		
Very satisfied	6 (18%)	12 (22%)		
Moderately satisfied	7 (21%)	9 (17%)		
Somewhat satisfied	6 (18%)	9 (17%)		
Neither satisfied nor dissatisfied	9 (27%)	15 (28%)		
Somewhat dissatisfied	3 (9%)	6 (11%)		
Moderately dissatisfied	1 (3%)	3 (6%)		
Very dissatisfied	1 (3%)	0		
Did product have an aftertaste?				
n			121	121
No aftertaste			90 (74%)	66 (55%)
Very mild aftertaste			22 (18%)	33 (27%)
Mild aftertaste			7 (6%)	10 (8%)
Neither mild nor strong aftertaste			0	3 (2%)
Slightly strong aftertaste			2 (2%)	6 (5%)
Moderately strong aftertaste			0	3 (2%)
Very strong aftertaste			0	0

Continued

Secondary Outcome Variable(s): Subject ratings of individual sensory attributes, immediate and delayed attributes questionnaires, <i>continued</i>				
	Immediate attributes questionnaire		Delayed attributes questionnaire	
	FF	FP	FF	FP
How satisfied with aftertaste? n			34	54
Very satisfied			7 (21%)	12 (22%)
Moderately satisfied			8 (24%)	9 (17%)
Somewhat satisfied			3 (9%)	7 (13%)
Neither satisfied nor dissatisfied			11 (32%)	15 (28%)
Somewhat dissatisfied			3 (9%)	9 (17%)
Moderately dissatisfied			2 (6%)	2 (4%)
Very dissatisfied			0	0
Did medicine run out of nose? n	121	121	121	121
None	61 (50%)	38 (31%)	63 (52%)	46 (38%)
Very slightly ran out of my nose	42 (35%)	38 (31%)	40 (33%)	39 (32%)
Slightly ran out of my nose	11 (9%)	28 (23%)	10 (8%)	24 (20%)
Neither slightly nor moderately ran out of my nose	2 (2%)	1 (<1%)	1 (<1%)	1 (<1%)
Moderately ran out of my nose	5 (4%)	11 (9%)	7 (6%)	4 (3%)
Markedly ran out of my nose	0	4 (3%)	0	4 (3%)
Very markedly ran out of my nose	0	1 (<1%)	0	3 (2%)
Did medicine run down throat? n	121	121	121	120
None	74 (61%)	69 (57%)	64 (53%)	55 (46%)
Very slightly ran down my throat	28 (23%)	29 (24%)	26 (30%)	37 (31%)
Slightly ran down my throat	11 (9%)	15 (12%)	12 (10%)	17 (14%)
Neither slightly nor moderately ran down my throat	3 (2%)	5 (4%)	1 (<1%)	3 (3%)
Moderately ran down my throat	3 (2%)	3 (2%)	5 (4%)	6 (5%)
Markedly ran down my throat	1 (<1%)	0	3 (2%)	1 (<1%)
Very markedly ran down my throat	1 (<1%)	0	0	1 (<1%)
Did product feel soothing? n	121	121	120	121
None	28 (23%)	24 (20%)	26 (22%)	25 (21%)
Very slight soothing feeling	28 (23%)	31 (26%)	34 (28%)	31 (26%)
Slight soothing feeling	25 (21%)	27 (22%)	25 (21%)	29 (24%)
Neither slight nor moderate soothing feeling	17 (14%)	16 (13%)	15 (13%)	11 (9%)
Moderate soothing feeling	15 (12%)	16 (13%)	11 (9%)	19 (16%)
Marked soothing feeling	4 (3%)	5 (4%)	5 (4%)	6 (5%)
Very marked soothing feeling	4 (3%)	2 (2%)	4 (3%)	0
Did product make want to sneeze? n	121	121		
No urgency to sneeze	87 (72%)	93 (77%)		
Very slight urgency to sneeze	17 (14%)	12 (10%)		
Slight urgency to sneeze	8 (7%)	10 (8%)		
Neither slight nor moderate urgency to sneeze	2 (2%)	2 (2%)		
Moderate urgency to sneeze	2 (2%)	2 (2%)		
Marked urgency to sneeze	3 (2%)	2 (2%)		
Very marked urgency to sneeze	2 (2%)	0		

Continued

Secondary Outcome Variable(s): Subject ratings of individual sensory attributes, immediate and delayed attributes questionnaires, <i>continued</i>				
	Immediate attributes questionnaire		Delayed attributes questionnaire	
	FF	FP	FF	FP
Did product cause nasal irritation? n			121	121
None			89 (74%)	78 (64%)
Very slight nasal irritation			18 (15%)	21 (17%)
Slight nasal irritation			6 (5%)	10 (8%)
Neither slight nor moderate nasal irritation			2 (2%)	3 (2%)
Moderate nasal irritation			3 (2%)	7 (6%)
Marked nasal irritation			2 (2%)	1 (<1%)
Very marked nasal irritation			1 (<1%)	1 (<1%)
How bothersome was nasal irritation? n			38	48
None			7 (18%)	7 (15%)
Very slightly bothersome			15 (39%)	22 (46%)
Slightly bothersome			9 (24%)	8 (17%)
Neither slightly nor moderately bothersome			2 (5%)	2 (4%)
Moderately bothersome			4 (11%)	6 (13%)
Markedly bothersome			0	1 (2%)
Very markedly bothersome			1 (3%)	2 (4%)
How satisfied with product? n			121	120
Very satisfied			44 (36%)	34 (28%)
Moderately satisfied			27 (22%)	23 (19%)
Somewhat satisfied			17 (14%)	27 (23%)
Neither satisfied nor dissatisfied			19 (16%)	21 (18%)
Somewhat dissatisfied			7 (6%)	8 (7%)
Moderately dissatisfied			5 (4%)	7 (6%)
Very dissatisfied			2 (2%)	0
How likely to comply if prescribed? n			121	120
Very likely to comply			63 (52%)	45 (38%)
Moderately likely to comply			19 (16%)	26 (22%)
Somewhat likely to comply			18 (15%)	16 (13%)
Neither likely nor unlikely to comply			7 (6%)	10 (8%)
Slightly unlikely to comply			4 (3%)	12 (10%)
Moderately unlikely to comply			4 (3%)	7 (6%)
Very unlikely to comply			6 (5%)	4 (3%)
<p>Safety Results: An adverse event (AE) was defined as any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Overall, 3/127 (2%) subjects reported AEs following FF nasal spray treatment, which included dizziness, headache and nasal congestion. Headache and nasal congestion, but not dizziness, were considered by the investigator to be drug-related. No AEs were reported following treatment with FP nasal spray. No AEs leading to permanent discontinuation of the study drug were reported during the study. No pregnancies were reported.</p>				

Adverse Events	FF (N=127)	FP (N=127)
Subjects with any AEs, n (%)	3 (2%)	0 (0%)
Dizziness	1 (<1%)	0 (0%)
Headache	1 (<1%)	0 (0%)
Nasal congestion	1 (<1%)	0 (0%)
<p>Serious Adverse Events: A serious adverse event (SAE) was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening, required hospitalisation, resulted in disability/incapacity, or was a congenital anomaly/birth defect. No SAEs were reported during the study.</p>		

Conclusions:

See publication below

Publications:

Meltzer E, Stahlman J, Leflein J, Meltzer S, Lim J, Dalal A, Prillaman B, Philpot E. A patient preference evaluation study comparing the sensory attributes of fluticasone furoate nasal spray with fluticasone propionate nasal spray. *Ann Allergy Asthma Immunol* 2008; 100(1) (Supplement 1):A89 (abstract)

Date updated: 6-Feb-2008