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Study No.: FFR105693		
Title: A Randomized, Single-blind, Cross-over, Multicenter Study to Validate the Preference Module of the Experience with Allergic Rhinitis Nasal Sprays Questionnaire (EARNs-Q) Administered to Adult Subjects with Seasonal Allergic Rhinitis during a Three-week Cross-over Study.		
Rationale: To validate the Preference Module of the EARNs-Q in adult subjects (≥ 18 years of age) with seasonal allergic rhinitis (SAR) taking 116mcg BID (232mcg/day) flunisolide nasal spray compared with 168 mcg BID (336mcg/day) beclomethasone dipropionate, monohydrate nasal spray.		
Phase: IV		
Study Period: 01 May 2006-29 June 2006		
Study Design: Randomized, Single-blind, Cross-over		
Centres: Eight (8) investigational sites in the northern California region of the United States		
Indication: Seasonal Allergic Rhinitis		
Treatment: Flunisolide (FLU, 232mcg/day) and beclomethasone dipropionate monohydrate (BDP, 336mcg/day) nasal sprays		
Objectives: Validation of the Preference Module of the EARNs-Q		
Primary Outcome/Efficacy Variable: Not applicable		
Secondary Outcome/Efficacy Variable(s): Mean reflective total nasal symptom scores over the 2 week treatment period		
Statistical Methods: Three populations were defined: the Efficacy Population, which was all subjects who completed both treatment periods and had efficacy and questionnaire data recorded in both treatment periods, The Intent-to-Treat population, which included all subjects who were randomized to study drug and formed the basis of all summaries of background and safety data, and the Validation Population, which included all subjects who completed at least 50% of the items in each questionnaire at each study visit.		
Study Population: Male and female subjects ≥ 18 years of age with seasonal allergic rhinitis (SAR)		
	BDP/FLU	FLU/BDP
Number of Subjects:		
Planned, N	90	90
Randomised, N	97	97
Completed, n (%)	44 (90)	45 (94)
Total Number Subjects Withdrawn, N (%)	5 (10)	3 (6)
Withdrawn due to Adverse Events n (%)	0	0
Withdrawn due to Lack of Efficacy n (%)	0	0
Withdrawn for other reasons n (%)	1 (2)	0
Demographics		
N (ITT)	93	91
Females: Males	49:48	
Mean Age, years (SD)	37.1 (12.56)	
Not Hispanic/Latino, n (%)	81 (84)	
Duration of SAR, n (%)		
≥ 2 to < 5 years	19 (20)	
≥ 5 to < 10 years	20 (21)	
≥ 10 years	58 (60)	

Primary Efficacy Results:					
Correlations of EARNs-Q Preference domains and Overall Preference item with change on TSQM and rTNSS					
	TSQM Domain Change Scores (N=89)				
EARNs-Q Preference Domains	Global Satisfaction	Convenience	Effectiveness	Side-effects	Change in Mean Daily rTNSS
Total	0.45	0.45	0.44	0.36	-0.39
Efficacy	0.56	0.30	0.59	0.26	-0.53
Sensory Perceptions	0.33	0.38	0.33	0.37	-0.27
Device Characteristics	0.29	0.49	0.24	0.26	-0.21
Spray Delivery	0.34	0.37	0.30	0.25	-0.27
Overall Product Preference (item)	0.54	0.35	0.52	0.30	-0.50
Correlation of EARNs-Q Preference domains and Overall Preference item with Experience domain change scores					
	EARNs-Q Experience Domain Change Scores (N=89)				
EARNs-Q Preference Domains	Total	Efficacy	Sensory Perceptions	Device Characteristics	Spray Delivery
Total	0.72	0.38	0.66	0.42	0.38
Efficacy	0.47	0.55	0.29	0.20	0.29
Sensory Perceptions	0.75	0.25	0.79	0.43	0.29
Device Characteristics	0.63	0.20	0.59	0.45	0.38
Spray Delivery	0.47	0.24	0.38	0.32	0.39
Overall Product Preference (item)	0.59	0.44	0.47	0.33	0.35
Secondary Efficacy Results for rTNSS:					
	BDP (N=89)	FLU (N=89)	LS Mean Difference (FLU-BDP)		
LS Mean (Std Err)	5.3 (0.28)	5.1 (0.28)			
LS Mean Difference			-0.2		
p-value			0.517		
95% CI			(-0.6,0.3)		
Safety Results:					
	BDP/FLU		FLU/BDP		
Most Frequent Adverse Events – On-Therapy	n (%)		n (%)		
Subjects with any AE(s), n(%)	16 (16)		17 (18)		
Any Event	8 (8)		10 (10)		
Headache	7 (7)		9 (9)		
Dizziness	1 (1)		0		

Dysgeusia	0	1 (1)
Sinus headache	1 (1)	0
Respiratory, thoracic and mediastinal disorders		
Any event	3 (3)	4 (4)
Nasal discomfort	0	2 (2)
Nasal dryness	1 (1)	1 (1)
Asthma	1 (1)	0
Cough)	1 (1%)	0
Epistaxis	1 (1)	0
Pharyngolaryngeal pain	0	1 (1)
Infections and infestations		
Any event	1 (1)	4 (4)
Eye infection	1 (1)	1 (1)
Upper respiratory tract infection	0	2 (2)
Diverticulitis	0	1 (1)
Gastrointestinal disorders		
Any event	2 (2)	3 (3)
Vomiting	1 (1)	1 (1)
Abdominal pain	0	1 (1)
Diarrhoea	0	1 (1)
Flatulence	1 (1)	0
Stomach discomfort	0	1 (1)
Musculoskeletal and connective tissue disorders		
Any event	1 (1)	3 (3)
Back pain	0	2 (2)
Arthralgia	0	1 (1)
Musculoskeletal stiffness	0	1 (1)
Myalgia	1 (1)	0
Injury, poisoning and procedural complications		
Any event	2 (2)	0
Joint sprain	1 (1)	0
Muscle strain	1 (1)	0
General disorders and administration site conditions		
Any event	0	1 (1)
Hangover	0	1 (1)
Renal and urinary disorders		
Any event	0	1 (1)
Nephrolithiasis	0	1 (1)
Reproductive system and breast disorders		
Any event	1 (1)	0
Dysmenorrhoea	1 (1)	0
Serious Adverse Events - On-Therapy		
n (%) [n considered by the investigator to be related to study medication]		
	BDP/FLU	FLU/BDP
Subjects with non-fatal SAEs, n (%)	0	0
Subjects with fatal SAEs, n (%)	0	0

Conclusion:

Headache was the most common AE that occurred during the treatment period. No subjects withdrew from the study due to an AE. There were no reports of serious adverse events or

deaths during the study.

Overall, the pattern of correlations between EARNNS-Q preference domains and change in TSQM and rTNSS domains supports the validity of the EARNNS-Q preference domains, with the largest correlations existing between analogous Preference and Experience change scores.

Publications:

No publication

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