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Use subject not patient throughout (except for the title which should be verbatim from the report)

Study No.: SAM108835	
Title: An Open-Label, Multi-Centre Study to Evaluate Patient Satisfaction with Fluticasone/Salmeterol HFA MDI with Counter in Adult Subjects (18 years of age and older) with Asthma or COPD	
Rationale: The addition of a counter to an MDI is intended to provide subjects with a reliable indicator of how many actuations are left in their inhalers throughout their use. GlaxoSmithKline (GSK) has developed an MDI counter designed to accurately count actuations and display the number of actuations remaining within FLUTICASONE/SALMETEROL HFA. This actual use subject handling study will evaluate the subject satisfaction of the MDI counter in asthma or COPD subjects. It will also evaluate the healthcare professionals' satisfaction with the counter in the management of their subjects.	
Phase: IV	
Study Period: 3 January 2007 – 9 August 2007	
Study Design: This was an open-label, single arm, multi-centre, 9 week subject handling study of Fluticasone/Salmeterol MDI with Counter	
Centres: The study was conducted at 2 sites across Australia	
Indication: Asthma or COPD	
Treatment: Subjects were assigned to a fixed dose of Fluticasone/Salmeterol HFA with Counter, 2 puffs, twice daily at Visit 2. The dose was determined by the Investigator with consideration of the screening and pre-study dose (50/25; 125/25 or 250/25). In addition, a separate Salbutamol HFA was provided for rescue use throughout the study period.	
Objectives: To evaluate subject and healthcare professional satisfaction with Fluticasone/Salmeterol HFA MDI with counter in adult subjects with asthma or COPD in Australia	
Primary Outcome: This study evaluated subject satisfaction of the Fluticasone/Salmeterol HFA with Counter MDI in subjects with asthma or COPD	
Secondary Outcome(s): Healthcare professional satisfaction of the Fluticasone/Salmeterol HFA with counter Subject compliance Safety evaluations (adverse events)	
Statistical Methods: Narrative and descriptive listings were provided for all endpoints. No statistical hypothesis, efficacy analysis or inferential analyses were conducted.	
Study Population: Subjects with a documented physician diagnosis of asthma or COPD, requiring the use of controller medication and long-acting beta-2 agonist for the relief of respiratory symptoms at Visit 1; no history of life threatening asthma/COPD; no recent upper or lower respiratory infection within the 2 weeks prior to visit 1 or between visit 1 and visit 2; and no systemic corticosteroid use.	
Number of Subjects:	Fluticasone/Salmeterol HFA with Counter MDI
Planned, N	150
Entered, N	132

Completed, n (%)	99/104 (95)	
Total Number Subjects Withdrawn, N (%)	33 (25)	
Withdrawn due to Adverse Events n (%)	3 (2)	
Withdrawn due to Lack of Efficacy n (%)	0	
Withdrawn for other reasons n (%)	30 (23)	
Demographics		
N (ITT)	104	
Females: Males	52:52	
Mean Age, years (SD)	54.5 (17.96)	
White/Caucasian/European, n (%)	102 (98.1)	
Asthma	77 (74)	
COPD	27 (26)	
Primary Results:		
No efficacy results were obtained in this study. The primary endpoint results for the subject satisfaction with the Fluticasone/Salmeterol HFA with Counter MDI are presented below.		
	HFA no counter N=103	HFA counter N=98
Do you feel anxious about the amount of asthma/COPD medication left in your inhaler? n (%)		
Yes	15 (14)	2 (2)
No	88 (85)	96 (92)
How confident are you that you have the number of asthma/COPD puffs or number of days of medication remaining in your inhaler? Scale 1-10 mean (SD)	5.3 (2.86)	8.5 (1.97)
How would you rate your satisfaction with the MDI provided? n (%)	23 (22)	7 (7)
Slightly satisfied	42 (40)	81 (78)
Strongly satisfied		
The MDI counter will allow me to monitor my medication use? n (%)	NA	9 (9)
Neutral		19 (18)
Slightly satisfied		70 (67)
Strongly satisfied		
Secondary Outcome Variable(s):		
Healthcare Professional Satisfaction with the Fluticasone/Salmeterol HFA with Counter MDI		
	HFA no counter N=104	HFA counter N=99
How confident are you that the subject was able to determine how much asthma/COPD medication remained in his/her inhaler? Visual analogue scale 1-10 mean (SD)	4.6 (3.07)	9.2 (1.65)
How would you rate your satisfaction with the MDI provided? n (%) Slightly satisfied	NA	14 (14)
Strongly satisfied		80 (77)
The MDI counter has allowed me to monitor the subject's medication use? n (%)	NA	11 (11)
Neutral		51 (49)
Slightly satisfied		30 (29)
Strongly satisfied		
Subject Compliance		

	HFA no counter N=104	HFA counter N=104
Proportion of subjects who responded "No" to the question "Have you missed any doses of your inhaler?" n (%)	68 (65)	64 (62)
Compliance assessed by dose counter. % (SD)	NA	85.8 (16.11)
Safety Results: An on therapy adverse event (AE) and serious adverse event (SAE) were defined as an AE/SAE with onset on or after the start date of study medication but not later than the follow-up contact date (7+/- 3 days post treatment).		
	Fluticasone/Salmeterol HFA with Counter MDI N=104	
Most Frequent Adverse Events – On-Therapy	n (%)	
Subjects with any AE(s), n(%)	29 (27.9)	
Upper Respiratory Tract Infection	11(10.6)	
Influenza	3 (2.9)	
Cough	2 (1.9)	
Lower Respiratory Tract Infection	2 (1.9)	
Pharyngolaryngeal Pain	2 (1.9)	
Serious Adverse Events -On-Therapy N (%) [n considered by the investigator to be related to study medications]		
	Fluticasone/Salmeterol HFA with Counter MDI N=104	
Subjects with non-fatal SAEs, n (%)	n (%) [related]	
Global Amnesia	1 (1) [0]	
Subjects with fatal SAEs, n (%)	n (%) [related]	
Any	0	

Conclusion: This study confirms a greater preference for use of an MDI with Counter by both patients and the Health Professionals (HP).

Patients were more satisfied with both ease of use and convenience of the MDI with Counter in the Intent-to-Treat population (ITT) 84.6%, and Completed Population (CP) 97.9%. The overall level of HP satisfaction with the MDI with Counter was 90.4% and 96% for the ITT and CP respectively.

Use of the MDI with Counter significantly raised the level of confidence in knowing how much medication remained in the device. Patients reported a high level of satisfaction knowing that the presence of a counter allows them to monitor medication use (85.6% ITT, 91.8% CP), and thus when it was time to refill their medication (90.4% ITT, 93.9% CP) and avoid running out. When the MDI without Counter was used, patients generally felt confident estimating how much medication was left in the device, but frequently overestimated this number.

Not knowing how much medication was left in the device led to anxiety in approximately one third of the patients. Suboptimal methods were reported by 84% of patients using the MDI without Counter to determine when the device would run out of medication (e.g. feeling like MDI was not working anymore, shaking, waiting till nothing was left in the MDI or could never tell).

The MDI with Counter helped patients take their medication as directed (68.3 % ITT, 75.5% CP) and allowed HP (77.8%) to better monitor the patient's medication use. In spite of this, only 57.7%

of the HP indicated that the MDI with Counter would form part of their patient management plan.

Although patient compliance with medication continued to be a challenge for the patients and the HP, this study reflected a 'real life' situation, with no specific intervention to improve patient compliance. It is therefore of interest to note that, on average, the patients took a high percentage of their expected doses (85.8% ITT, 95.4% CP) when treatment compliance was assessed by the MDI with Counter.

In summary, the MDI with Counter led to a higher level of satisfaction for both HP and patients. The counter provides an additional tool to help monitor medication use and improve patient management. Within 1 year after study completion this section will either refer you to a publication or contain text interpreting the trial results.

Publications: Nil to date