STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Symbicort® Turbuhaler®
ACTIVE INGREDIENT: budesonide/formoterol

Study No: D5890C00017
A Pharmaceopidemiological Study in Patients Who Use Symbicort Turbuhaler as Maintenance and Reliever Therapy (Symbicort SMART) Capturing Over Use and Under Use Via the General Practice Research Database

Developmental Phase: IV
Study Completion Date: 5 May 2010
Date of Report:

OBJECTIVES:

To investigate possible over use and under use of Symbicort SMART treatment. Symbicort SMART treatment involves the use of a budesonide/formoterol combination as both a maintenance and reliever therapy.

METHODS:

Observational Model: Case-Only

The first 1000 Symbicort SMART users were identified in the General Practice Research Database.

Potential overuse was assessed as absolute utilisation on an individual prescription basis relative to a threshold, and as an as required use above maintenance dose.

Potential under use was assessed by evidence of asthma related hospitalisation.

RESULTS:

Full data for these patients was extracted in February 2010 when all patients had a minimum follow-up of 365 days., with the following timepoints achieved:
        First Subject First Prescription (index date): 4th June 2007
        Last Subject First Prescription (index date): 14th January 2009

Table 2: Basic demographics for the 1000 user cohort

Gender	
Male	372 (37.2%)
Female	628 (62.8%)
Age at index date (years)	
Mean	46.52 (45.37,47.67)
median	46 (4.6%)
0-5	1 (0.1%)
6-11	8 (0.8%)
12-17	43 (4.3%)
18-35	248 (24.8%)
36-53	327 (32.7%)
54-71	273(27.3%)
72-89	97(9.7%)
90+	3(0.3%)

Symbicort SMART dosage for Symbicort is being utilised across all age groups.
More women than men were prescribed Symbicort SMART, and the mean age was 46.52
years. 5.2% of patients were under 18 years of age at their index prescription.
4.2% of patients left the practice prior to the end of their 365 day follow-up, and a total
follow-up time of 978 person years was available.

Table 3: Symbicort SMART Prescribing characteristics

Symbicort SMART (1 year follow-up)	
Number of prescriptions	4,308
Total follow up time	978.0 person years
Mean number of prescriptions per patient (95% CI)	4.31 (4.07,4.54)
Mean number of Prescriptions per patient (patients with full follow up) (95% CI)	4.38 (4.12, 4.63)
Prescription number of inhalations	
60	224 (5.2%)
120	4,082 (94.8%)

During this time 4,308 Symbicort SMART prescriptions were issued, 94.8% of which
were for 120-inhalations Turbuhaler. With regard to strength, 80.3 % of prescriptions
were for the 200/6 microgram strength product. 14.5% were for the 100/6 microgram
strength. 5.2% were for the 400/12 microgram strength (for which Symbicort SMART is
unlicensed). These high strength prescriptions were prescribed to 33 patients.

Based on the analysis of single prescriptions, 175 patients were flagged as possible over
users. Based on the analysis of all of the patients' prescriptions over the entire follow-up
periods, only 8 patients were identified as potential over users where their use fell in the
band including more than 8 inhalations per day. Potential underuse, based on
hospitalisations with discharge diagnosis of asthma, was identified for 9 patients.