AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT:
Symbicort™, Seretide™, Combair™/Foster™

ACTIVE INGREDIENT:
budesonide/formoterol, salmeterol/fluticasone, beclomethasone/formoterol

Study No: NIS-RCZ-SYM-2010/1
Utilization of **F**ixed c**O**mbination (budesonide/formoterol and salmeterol/fluticasone and beclomethasone/formoterol) in treatment of asthma patients in real life condition in the Czech Republic (UFO)

Developmental Phase: non-interventional study
Study Completion Date: 30th June 2011
Date of Report: 9th December 2011

RATIONALE FOR THIS NON-INTERVENTIONAL STUDY

Moderate and severe asthma bronchiale is treated by fixed combination (budesonide/formoterol or salmeterol/fluticasone) in the Czech Republic.

We do not have any data about real life utilization of fixed combination in asthma treatment in the Czech Republic.

Hypothesis is that a doctor should describe to each patients per year:

- six units of fixed combination budesonide/formoterol (100/6 and 200/6) and twelve units of fixed combination budesonide/formoterol (400/12) or
- seven units of fixed combination budesonide/formoterol in approach SMART or
- twelve units of fixed combination salmeterol/fluticasone or
- twelve units of fixed combination beclomethasone/formoterol.

With regard to current prices the treatment by fixed combination budesonide/formoterol should cost less.

We propose to conduct the NIS looking into utilization of fixed combination in asthma treatment with special towards Symbicort Turbuhaler.

OBJECTIVES:

Primary objective

Utilization of fixed combination (budesonide/formoterol, salmeterol/fluticasone and beclomethasone/formoterol) in the treatment of asthma patients per year.

Main secondary objectives

To describe asthma treatment in the Czech Republic in patients who were prescribed a fixed combination therapy.

METHODS:

This study is a retrospective epidemiological study looking into patients´ medical records kept by a hospital/institution/physician. There are no scheduled visits for any patient participating in the study.

Patient population selection criteria

Inclusion criteria

For inclusion into this non-interventional study, subjects must fulfil all of the following criteria:

1. Male or female aged 6 years or over
2. Asthma bronchiale, classification of severity - moderate or severe persistent
3. Documented fixed combination (budesonide/formoterol or salmeterol/fluticasone) therapy for at least 18 months

Exclusion criteria

None

Retrospective data for eligible patients will be reviewed by participating investigators, physicians taking care of their patients, and recorded in the electronic CRF.

Only patients who have been treated for asthma bronchiale (classification of severity - moderate or severe persistent asthma) with fixed combination for at least one year could be included into the study. There are no scheduled visits for any patient participating in the study.

Every participating investigator will recruit up to 10 patients to the NIS.

From the moment the participating investigator joins the NIS he/she selects the first ten patients treated by fixed combination budesonide/formoterol or salmeterol/fluticasone or beclomethasone/formoterol for at least 18 months who come to a regular visit.

RESULTS:

145 pulmologists and 132 allergists departments for outpatients have participated in this non-interventional study.

Every participating investigator recruited 10 patients to the study. The total number of recruited asthmatic outpatients older than 6 years is 2786 (male 44.5%, female 55.5%; child and adolescents 13.1%, seniors 12.8%; current smokers 20,9 %, ex-smokers 7.7%). All patients who come to a regular visit were treated with one of three fixed combination for at least 18 months.

There were 38 resp. 1.8 % pts. with intermittent asthma, 524 resp. 18.8% pts. with mild persistent asthma, 1884 resp. 67.6% pts. with moderate persistent asthma, 340 resp. 12.2 % pts. with severe persistent asthma including 94 resp. 3.4% pts. with asthma difficult to treat.

The number of patients treated with fixed combination budesonide/ formoterol was 1694 60.8% pts. (55.9% pts. in convectional regime, 44.1% pts. in the SMART regime), 1040 resp. 37.3% pts. were treated with fixed combination salmeterol/fluticason, 52 resp. 1.87% pts. were treated with beclomethasone/formoterol.

Median number of packs prescribed per year to patients with asthma for fixed combination budesonide/formoterol in conventional regime was 7, in SMART regime was 7, for fixed combination salmeterol/fluticason was 12, for fixed combination beclomethasone/formoterol was 6.

Total compliance of using fixed combination was 53.3%, compliance of using fixed combinations in convetional regimes was 48.5%, and compliance of using budesonide/formoterol in the SMART regime was 67.6%.