SWITCHING INHALER – REAL-WORLD EVIDENCE ON EASYHALER®

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REAL-WORLD STUDY IN SWEDEN: EFFECTIVENESS OF SWITCHING FROM BUDESONIDE-FORMOTEROL TURBUHALER® TO BUDESONIDE-FORMOTEROL EASYHALER®


AIM:
To demonstrate non-inferiority of asthma control when switching from budesonide-formoterol Turbuhaler to an equivalent dose budesonide-formoterol Easyhaler (160/4.5 or 320/9 mcg/dose).

STUDY DESIGN:
• An open, prospective, non-interventional, multicentre, single arm study among 125 adult patients with stable asthma in Swedish primary care.
• Inclusion criteria: Patients prescribed with budesonide-formoterol Turbuhaler ≥6 months prior to study.
• 3 study visits during 3 months.
• Inhaler training performed according to the centre’s normal routine.

PRIMARY ENDPOINT:
Non-inferiority of asthma control after switch
• ACT

SECONDARY ENDPOINTS:
Asthma-related quality of life, lung function and inhaler perception among physicians and patients
• mini-AQLQ
• FEV1, FVC, FEV1% and FVC% predicted normal
• Learning and usage questionnaires

ACT = Asthma Control Test; mini-AQLQ = mini-Asthma Quality of life Questionnaire;
FEV1 = forced expiratory volume in 1 second; FVC = forced vital capacity

REAL-WORLD STUDY IN SWEDEN: SIGNIFICANT CLINICAL AND QoL IMPROVEMENT AMONG PATIENTS WITH ASTHMA TREATED WITH BUDERSONIDE-FORMOTEROL EASYHALER

- 117 patients completed the study.
- The proportion of patients with well-controlled asthma increased from 53.0% at baseline to 70.9% over the 12-week treatment period.
- Mean ACT score improved from 18.9 to 20.7 (P<0.0001).
- Mean mini-AQLQ mean score improved from 5.4 to 5.8 (P<0.0001).

**Asthma Control (ACT score)**

<table>
<thead>
<tr>
<th>Baseline (Switch)</th>
<th>12 Weeks with Easyhaler Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>VERY POORLY CONTROLLED (ACT score ≤15)</td>
<td>19</td>
</tr>
<tr>
<td>NOT WELL-CONTROLLED (ACT score 16-19)</td>
<td>28</td>
</tr>
<tr>
<td>WELL-CONTROLLED (ACT score ≥20)</td>
<td>53</td>
</tr>
<tr>
<td>PATIENTS (%)</td>
<td>71</td>
</tr>
</tbody>
</table>

**Asthma QoL (mean mini-AQLQ score, range 0-6)**

<table>
<thead>
<tr>
<th>Baseline (Switch)</th>
<th>12 Weeks with Easyhaler Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>mini-AQLQ SCORE</td>
<td>5.4</td>
</tr>
<tr>
<td></td>
<td>5.8</td>
</tr>
</tbody>
</table>

*P<0.0001 for mean ACT score.
ACT = Asthma Control Test; mini-AQLQ = mini-Asthma Quality of Life Questionnaire

REAL-WORLD STUDY IN SWEDEN: LUNG FUNCTION PARAMETERS REMAINED STABLE ACROSS THE TREATMENT PERIOD

- Evaluation of lung function among 117 patients with asthma switching to budesonide-formoterol Easyhaler from budesonide-formoterol Turbuhaler.
- Outcomes assessed for Easyhaler after 12 weeks of Easyhaler therapy (visit 3), and for Turbuhaler at visit 1.

Data presented as mean (95% CI).
FEV1 = forced expiratory volume in 1 second; FVC = forced vital capacity

REAL-WORLD STUDY IN SWEDEN:
OVERALL PATIENT SATISFACTION WITH EASYHALER 64%
COMPARED TO 41% WITH TURBUHALER

OVERALL CONCLUSIONS OF THE STUDY


I. Non-inferiority criteria was met.

II. In fact, switching to budesonide-formoterol Easyhaler resulted in significant improvement in asthma control and asthma-related quality of life (P<0.0001).

III. The majority of patients assessed the Easyhaler as easy to learn and prepare for use and were satisfied with it.
CAN CHOICE OF AN INHALER AFFECT TREATMENT EFFECTIVENESS AND HENCE PATIENT’S QUALITY OF LIFE?

FURTHER STUDIES WITH EASYHALER

EASYHALER

WEHALE.LIFE
REAL-WORLD STUDY IN POLAND:
SIGNIFICANT CLINICAL IMPROVEMENT AMONG PATIENTS WITH ASTHMA TREATED WITH BUDERONIDE-FORMOTEROL EASYHALER

A non-randomized, open-label, non-interventional multicentre study assessing clinical efficacy of budesonide-formoterol Easyhaler in outpatient care.

2,200 adult patients with asthma treated with budesonide-formoterol Easyhaler.

Asthma control was evaluated at the first healthcare visit as well as after 12 weeks of Easyhaler therapy (visit 3).

ACT = Asthma Control Test

REAL-WORLD STUDY IN HUNGARY: SIGNIFICANT CLINICAL IMPROVEMENT WAS SHOWN FOR PATIENTS WITH ASTHMA OR COPD SWITCHING FROM PREVIOUS INHALER TO EASYHALER

A post-hoc subanalysis of a previously reported non-randomised, open-label, non-interventional multicentre study assessing effectiveness of budesonide-formoterol Easyhaler in daily clinical practice.

Evaluation of disease control (ACT or CAT) among 398 patients with asthma and 563 patients with COPD switching to budesonide-formoterol Easyhaler from their previous inhaler.

\[P < 0.0001\] for both asthma and COPD comparisons (visit 1 vs. visit 3).

ACT = Asthma Control Test; CAT = COPD Assessment Test

WHAT IS THE ROLE OF INHALER USE FACTORS, SUCH AS INHALER TECHNIQUE OR PATIENT PREFERENCE AND SATISFACTION?

FURTHER STUDIES WITH EASYHALER

WEHALE.LIFE
REAL-WORLD STUDY IN SWEDEN: OVERALL PATIENT SATISFACTION WITH EASYHALER 64% COMPARED TO 41% WITH TURBUHALER

- 125 adult patients with stable asthma treated with budesonide-formoterol Turbuhaler for ≥6 months prior to recruitment.
- Treatment switched to an equal dose budesonide-formoterol Easyhaler therapy.
- Baseline assessments and guided switch performed at visit 1.
- Study outcomes evaluated after 12 weeks of Easyhaler therapy (visit 3). Patient satisfaction questionnaires performed for Easyhaler at visit 3 and for Turbuhaler at visit 1.\(^\text{1,2}\)

REAL-WORLD STUDY IN HUNGARY: MORE THAN 90% OF PHYSICIANS DESCRIBED EASYHALER AS VERY EASY OR EASY TO USE, WITH 74% OF THEIR PATIENTS HAVING LEARNED THE TECHNIQUE WITHIN 5 MINUTES OF TEACHING

Evaluation of ease of use and time taken to teach the Easyhaler technique among 1,043 patients (621 adult patients with asthma, 778 with COPD, and 99 patients with ACO).

*Assessed at visits 1-3.
**Assessed at visit 1 after initial teaching of Easyhaler use. ACO = asthma-COPD overlap.

REAL-WORLD STUDY IN HUNGARY:
SATISFACTION INCREASED SIGNIFICANTLY AMONG PATIENTS
WITH ASTHMA OR COPD AFTER SWITCHING TO EASYHALER

Evaluation of patient satisfaction among 310 patients with asthma and 435 patients with COPD switching to budesonide-formoterol Easyhaler from their previous inhaler.

P<0.0001 for all comparisons (visit 1 vs. visit 3).

REAL-WORLD STUDY IN HUNGARY: MAJORITY OF PATIENTS WITH ASTHMA OF ALL AGES AS WELL AS COPD PATIENTS FOUND EASYHALER VERY EASY OR EASY TO LEARN AND USE

- Two open, uncontrolled, non-randomised multicentre studies assessing patients handling of inhaler and patient satisfaction.
- 797 adult and elderly patients with asthma or COPD receiving daily treatment with formoterol Easyhaler for 3 months.
- 219 children and adolescents using salbutamol Easyhaler as needed for 3–12 months.

EASE OF SWITCHING BETWEEN EASYHALER THERAPIES - ONE DEVICE TO MASTER

Easyhaler DPI provides controller (ICS), reliever (SABA, LABA), and combination therapies (ICS-LABA).1–6

The Easyhaler product range allows therapy optimisation without the need to learn a new inhaler technique.

OVERALL CONCLUSIONS FROM THE REAL-WORLD SWITCH STUDIES WITH EASYHALER

I. Switching to Easyhaler is clinically efficient among patients with asthma or COPD.1-4

II. Patients switching to Easyhaler were more likely to achieve overall disease control and improved QoL compared to their previous inhaler device.1-3

III. Majority of patients preferred Easyhaler2,3 and were satisfied with it1-5.

A prospective, open-label, non-interventional multicentre study among over 300 adult patients with asthma or COPD conducted in Germany and Sweden.

**AIM:**
To assess the clinical effectiveness of salmeterol-fluticasone Easyhaler to achieve and maintain asthma or COPD control, to evaluate the impact of switching on quality of life, patient satisfaction and preference, as well as to study physician/nurse perception on the overall use of salmeterol-fluticasone Easyhaler.

**STUDY DESIGN:** 3 study visits during 3 months

<table>
<thead>
<tr>
<th>VISIT 1</th>
<th>VISIT 2</th>
<th>VISIT 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline visit</td>
<td>Interim visit at 2 weeks</td>
<td>Final visit at 12 weeks</td>
</tr>
<tr>
<td>Screening and baseline</td>
<td>Inhaler technique checking and</td>
<td>Final assessments</td>
</tr>
<tr>
<td>assessments</td>
<td>training</td>
<td></td>
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ClinicalTrials.gov Identifier: NCT03755544
https://clinicaltrials.gov/ct2/show/NCT03755544?cond=asthma&spons=Orion+Pharma&rank=2
THANK YOU

EASYHALER

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