

# COMPARATIVE EFFECTIVENESS AND SAFETY OF BUDESONIDE STERINEBS® VS. PULMICORT RESPULES® IN A US POPULATION OF ASTHMA PATIENTS.

**First published:** 14/10/2014

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/26273>

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### **EU PAS number**

EUPAS7678

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### **Study ID**

26273

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### **DARWIN EU® study**

No

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## Study countries

United States

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## Study description

Historic cohort, US database study comparing effectiveness and safety of nebulised medication labelled by TEVA Ltd (Budesonide SteriNeb®) against the originator product (Pulmicort Respules®), in patients with a diagnosis for asthma.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

**First published:** 06/10/2015

**Last updated:** 19/08/2024

**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**ENCePP partner**

## Contact details

### **Study institution contact**

David Price

Study contact

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### **Primary lead investigator**

David Price

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 07/05/2014

Actual: 07/05/2014

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### **Study start date**

Planned: 30/06/2014

Actual: 07/07/2014

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### **Data analysis start date**

Planned: 15/08/2014

Actual: 22/08/2014

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### **Date of interim report, if expected**

Planned: 26/09/2014

Actual: 26/09/2014

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### **Date of final study report**

Planned: 03/11/2014

Actual: 31/10/2014

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

TEVA Ltd

## Study protocol

[R04913\\_Budesonide Sterinebs\\_Protocol v04.pdf](#)(637.77 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Unknown

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness  
Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The aim of this study is to compare Budesonide SteriNeb® with its originator, Pulmicort Respules®. The primary objective is to assess whether effectiveness (in terms of exacerbations) of Budesonide SteriNeb® is non-inferior to that of Pulmicort Respules® in both adult and children diagnosed with asthma.

## Study Design

**Non-interventional study design**

Cohort  
Other

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**Non-interventional study design, other**

Historical cohort database study

## Study drug and medical condition

## **Name of medicine, other**

Budesonide Sterinebs, Pulmicort Respules

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## **Medical condition to be studied**

Asthma

# Population studied

## **Short description of the study population**

People who have been diagnosed with asthma and have been prescribed Pulmicort Respules®. Patients must meet the following criteria:

1. Aged 1-80 years

Adult population: 12-80 years

Paediatric population:  $\geq 1$  and  $< 12$  years

2. Diagnosis for asthma (at any time), based on ICD9 codes (Annex 1)

3. Change sub-cohort:  $\geq 1$  prescription for Pulmicort Respules® in baseline (1 year prior to IPD) and  $\geq 1$  prescriptions for Budesonide SteriNeb® at IPD

4. Continuing sub-cohort:  $\geq 1$  prescription for Pulmicort Respules® during baseline (1 year prior to IPD) and  $\geq 1$  continued prescription for Pulmicort Respules® at IPD

5. Initiation sub-cohorts: no prescriptions for ICS nebulisers in baseline (1 year prior to IPD) and  $\geq 1$  prescription for either Budesonide SteriNeb® or Pulmicort Respules® at IPD

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## **Age groups**

Children (2 to  $< 12$  years)

Adolescents (12 to  $< 18$  years)

Adults (18 to  $< 46$  years)

Adults (46 to  $< 65$  years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

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### **Special population of interest**

Other

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### **Special population of interest, other**

Asthma patients

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### **Estimated number of subjects**

13019

## Study design details

### **Outcomes**

Primary outcome of this study is "effectiveness", evaluated in terms of:(1) Asthma-related hospitalisation rate in the outcome period, and(2) Severe exacerbation (ATS/ERS definition) rate in the outcome period.Please see the attached protocol for full definitions of these outcomes, Secondary outcome of this study is "safety", evaluated in terms of Adverse Events (AEs).These will include AEs known to be related to Budesonide SteriNeb® and Palmicort Respules®, as specified in their respective summary of product characteristics. Please see the attached protocol for a fuller definition of this outcome.

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### **Data analysis plan**

Statistically significant results will be defined as  $p < 0.05$  and trends as  $0.05 \leq p < 0.10$  Summary statistics will be produced for all baseline and outcome variables, as a complete dataset and by therapy. Treatment groups will be compared using t-test / Mann Whitney U-test (depending on distribution) for variables measured on the interval/ratio scale and using a chi square test for

categorical variables. Outcomes analyses: patients may be matched on demographics and key measures of disease severity to minimise confounding, using random selection process through SAS statistical software to avoid selection bias. Effectiveness and safety outcomes in the outcome period will be compared between treatment groups using a Conditional Poisson regression model. The model will use empirical standard errors (for more conservative confidence interval estimations) and adjustments will be made for potential baseline confounders. The adjusted rate ratio with 95% confidence interval will be reported

## Data management

### Data sources

#### **Data source(s), other**

Clinformatics™ Data Mart (CDM) database United States

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#### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

### Use of a Common Data Model (CDM)

#### **CDM mapping**

No

### Data quality specifications



**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown