

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pulmicort Turbohaler 100 micrograms Inhalation Powder.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains budesonide 100 micrograms.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Inhalation Powder.

Product imported from Spain, the UK, Hungary and Poland:

Breath-actuated metered dose inhaler. White to off-white spherical granules, which break into a fine powder on inhalation.

4 CLINICAL PARTICULARS

As per PA0970/050/005

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/050/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

- Do not store above 30°C
- Replace the cover properly after use.

6.5 Nature and contents of container

200 dose presentation

Container consisting of a cover screwed onto a bottom plate. Inside this is the inhaler with its main parts: a mouthpiece, a dosing mechanism and a substance store.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

See section 4.2.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/100/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 February 2003

Date of last renewal: 21 February 2008

10 DATE OF REVISION OF THE TEXT

December 2014