

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pulmicort Turbohaler 200 micrograms Inhalation Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains budesonide 200 micrograms.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation Powder.

Product imported from Italy:

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

4 CLINICAL PARTICULARS

As per PA 0970/050/006

5 PHARMACOLOGICAL PROPERTIES

As per PA 0970/050/006

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 shall be 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

The outer protecting parts of the container consist of a tubular cover screwed onto a bottom plate. These parts are made of polyethylene. Inside this is the inhaler with its main parts, a mouthpiece, a dosing mechanism and a substance store. Each inhaler contains 100 metered doses.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.
See Section 4.2 of PA0970/050/006.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/100/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st July 2015

10 DATE OF REVISION OF THE TEXT