

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 200 micrograms of budesonide.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation Powder.

Product imported from Bulgaria:

Breath actuated metered dose inhaler.

White to off white spherical granules which break into a fine powder on inhalation.

4 CLINICAL PARTICULARS

As per PA1019/017/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/017/004

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 inhaler 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 brown bottom plate. These parts are made of plastic. Inside this is the inhaler which consists of a mouthpiece, dosing mechanism and a substance store. Each inhaler contains 100 metered doses.

6.6 Special precautions for disposal

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/497/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th January 2023

10 DATE OF REVISION OF THE TEXT