

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Symbicort Turbohaler, 400 micrograms/12 micrograms/inhalation, inhalation powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each delivered dose (the dose that leaves the mouthpiece) contains: budesonide 320 micrograms/inhalation and formoterol fumarate dihydrate 9 micrograms/inhalation.

Each metered dose contains: budesonide 400 micrograms/inhalation and formoterol fumarate dihydrate 12 micrograms/inhalation.

Excipient with known effect

Lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder

Product imported from Slovakia

White powder

4 CLINICAL PARTICULARS

As per PA1019/020/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/020/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate (which contains milk proteins)

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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Symbicort Turbohaler is an inspiratory flow-driven, multidose powder inhaler.

The inhaler has a white body with a red turning grip.

Each carton contains 1 inhaler containing 60 doses.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Merit Pharmaceuticals Limited
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Kettles Lane
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23080/021/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th August 2020

10 DATE OF REVISION OF THE TEXT

May 2021