

Summary of Product Characteristics



This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1 NAME OF THE MEDICINAL PRODUCT

Spiolto Respimat 2.5 microgram/2.5 microgram, inhalation solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The delivered dose is 2.5 microgram tiotropium (as bromide monohydrate) and 2.5 microgram olodaterol (as hydrochloride) per puff.

The delivered dose is the dose which is available for the patient after passing the mouthpiece.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation solution

Product imported from the United Kingdom
Clear, colourless, inhalation solution

4 CLINICAL PARTICULARS

As per PA0775/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0775/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Disodium edetate
Purified water
1M Hydrochloric acid (for pH-adjustment)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the inhaler, cartridge and outer package of the product on the market in the country of origin.
In-use shelf life: 3 months

6.4 Special precautions for storage

Do not freeze.

6.5 Nature and contents of container

Container in contact with the medicinal product:

Solution filled into a cartridge. Each cartridge contains 4 ml inhalation solution

Pack size:

Single pack: 1 Respimat inhaler and 1 cartridge, providing 60 puffs (30 medicinal doses)

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon (UK) Ltd
Unit 18
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Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/048/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st June 2018

10 DATE OF REVISION OF THE TEXT