Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pulmicort Respules 1 mg /2 ml Nebuliser Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Pulmicort Respules 1 mg: Budesonide, 500 micrograms/ml.
Each 2 ml Respule contains 1 mg Budesonide.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nebuliser suspension.

Product imported from Greece

White to off-white sterile suspension in plastic single dose units.

4 CLINICAL PARTICULARS

As per PA1019/017/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/017/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethylenediaminetetraacetate disodium salt
Sodium chloride
Polysorbate 80
Citric acid anhydrous
Sodium citrate
Water for Injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date for this product shall be the date shown on the sachets and outer package of the product on the market in the country of origin.
Use within 3 months of opening the foil envelope.
If only 1ml of suspension is used, the remaining suspension is not sterile and should be discarded.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze. Store in the original package in order to protect from light. Units should be stored in an upright position and should be protected from freezing.

6.5 Nature and contents of container

The container is a low-density polyethylene single-dose plastic vial. Each plastic vial contains 2 ml of suspension. Each ml contains 0.5 mg budesonide. The package contains 5 plastic vials in an aluminium envelope. Each box contains 4 sachets.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

Ultrasonic nebulisers are not suitable for the administration of Pulmicort Respules and therefore are not recommended.

Pulmicort Respules can be mixed with 0.9% saline and with solutions for nebulisation of terbutaline, salbutamol, fenoterol, acetylcysteine, sodium cromoglycate and ipratropium bromide. The admixture should be used within 30 minutes (see section 4.2 of PA1019/017/002s SmPC).

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3,
Harcourt Centre,
Harcourt Road,
Dublin 2,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/059/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th May 2023

10 DATE OF REVISION OF THE TEXT