Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pulmozyme 2500 U/2.5 ml nebuliser solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains 2500 U (corresponding to 2.5 mg) of dornase alfa per 2.5 ml corresponding to 1000 U/ml or 1 mg/ml.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nebuliser solution.

Product imported from Greece and Belgium:

Clear, colourless to slightly yellowish solution.

4 CLINICAL PARTICULARS

As per PA2307/005/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2307/005/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride
Calcium Chloride Dihydrate
Water for Injections

6.2 Incompatibilities

Pulmozyme is an unbuffered aqueous solution and should not be diluted or mixed with other drugs or solutions in the nebuliser bowl. Mixing of this solution could lead to adverse structural and/or functional changes in Pulmozyme or the admixed compound.

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

Store in a refrigerator (2 °C - 8 °C).

Keep the ampoule in the outer carton in order to protect from light.

A single brief exposure to elevated temperatures (less than or equal to 24 hours at up to 30 °C) does not affect product stability.

6.5 Nature and contents of container

2.5 ml of nebuliser solution in a plastic ampoule.
Pack size of 6.

6.6 Special precautions for disposal and other handling

The contents of one 2.5 mg (2500 U) single-use ampoule of Pulmozyme sterile solution for inhalation should be inhaled once a day using a recommended nebuliser.

Pulmozyme should not be mixed with other drugs or solutions in the nebuliser (see section 6.2).

- Pulmozyme may be used in conjunction with a jet nebuliser/compressor system, such as the Hudson T Up-draft II/Pulmo-Aide, Airlife Misty/Pulmo-Aide, customised Respirgard/Pulmo-Aide, or AcornII/Pulmo-Aide.

- Pulmozyme may also be used in conjunction with a reusable jet nebuliser/compressor system, such as the Pari LL/Inhalierboy, Pari LC/Inhalierboy or Master, Aiolos/2 Aiolos, Side Stream/CR50 or MobilAire or Porta-Neb.

- The Pari eFlow Rapid nebuliser, a general purpose electronic vibrating membrane nebuliser may be used. Parity between the eFlow Rapid electronic nebuliser and the LC Plus jet nebuliser has been demonstrated *in vitro* and *in vivo*. The average droplet size distribution of the aerosol generated by the eFlow Rapid nebuliser compared with the LC Plus jet nebuliser is shown below, using an adult breath simulator profile. The mass median aerodynamic diameter (MMAD) was 4.8 ± 0.4 µm (n=16) for eFlow Rapid and 4.6 ± 0.4 µm (n=12) for LC Plus. The geometric standard deviation (GSD) was 1.80 ± 0.11 for eFlow Rapid and 2.14 ± 0.04 for LC Plus. The drug delivery rate was 380 ± 60 µg/min (n=88) for eFlow Rapid and 93 ± 16 µg/min (n=40) for LC Plus. The total drug delivered was 567 ± 62 µg for eFlow Rapid and 570 ± 80 µg for LC Plus. The Pari eFlow Rapid nebuliser should be used with the Pari EasyCare cleaning accessory and cleaning should be performed every seventh nebulisation cycle (a cycle being defined as a nebulisation of a single ampoule of Pulmozyme followed by cleaning and disinfecting in accordance with the PARI eFlow Rapid nebuliser system instruction for use). Using the eFlow Rapid nebuliser without EasyCare cleaning accessory may lead to lower and more variable dose delivery.

- Ultrasonic nebulisers may be unsuitable for delivery of Pulmozyme because they may inactivate Pulmozyme or have unacceptable aerosol delivery characteristics.

The manufacturers' instructions on the use and maintenance of the nebuliser and compressor should be followed.

Containment of the aerosol is not necessary.

Pulmozyme ampoules are for single administration only. Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/433/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th August 2018

10 DATE OF REVISION OF THE TEXT

February 2023