Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Flixotide Nebules 0.5mg/2ml Nebuliser Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each nebule contains 0.5mg Fluticasone propionate in 2ml suspension.
Each ml of suspension contains 0.25mg Fluticasone propionate.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Nebuliser Suspension (Nebuliser Liquid)
Product imported from Greece, Italy and Romania:
White, opaque suspension.

4 CLINICAL PARTICULARS

As per PA1077/044/016

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/044/016

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 20
Sorbitan monolaurate
Monosodium phosphate dihydrate
Dibasic sodium phosphate
Sodium Chloride
Water for Injection

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except these mentioned in section 6.6.

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.
Once Nebules have been removed from their foil flow wrap pack, they should be used within 28 days. Opened Nebules should be used immediately.
If diluted with sodium chloride injection, use immediately (see section 4.2 of PA1077/044/016 and section 6.6)

6.4 Special precautions for storage

Do not store above 30°C.
Store in the original container to protect from light.

Do not freeze.
Store upright.

6.5 Nature and contents of container

Flixotide Nebules are presented in 2.5ml medical grade low density polythene containers. Each nebule contains 2ml of solution. Each cardboard carton contains two foil flow wrap packs. Each foil flow wrap pack contains a strip of five Nebules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Refer to the manufacturer's instructions for nebuliser use.
It is important to ensure the contents of your Nebule are well mixed before use.

While holding the Nebule horizontally by the labelled tab, "flick" the other end a few times and shake. Repeat this process several times until the entire contents of the Nebule are completely mixed.

Shake gently before use.

To open-twist tab at the top of the Nebule.

Dilution:
Dilute with Sodium Chloride Injection BP immediately before use, if required. The diluted product should be a white semi-opaque suspension.
Do not use the suspension if discoloured.
Discard unused suspension in bowl of nebuliser.
It is advisable to administer via a mouth piece.
If using a face mask, protect skin with barrier cream, or wash face thoroughly after treatment.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/073/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 November 2006

Date of last renewal: 20 November 2011

10 DATE OF REVISION OF THE TEXT

March 2017