Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Flixotide Nebules 2 mg/ 2 ml Nebuliser Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each nebule contains 2mg Fluticasone propionate in a 2ml suspension.
Each ml of suspension contains 1mg Fluticasone propionate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nebuliser Suspension (Nebuliser Liquid)
Product imported from Greece

A white, opaque suspension.

4 CLINICAL PARTICULARS

As per PA1077/044/017.

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/044/017.

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 for this product shall be the date shown on the pouch 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 and 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.
Once Nebules have been removed from their foil flow wrap pack, they should be protected from light and used within 28 days.
Opened Nebules should be used immediately.
Store upright.

6.5 Nature and contents of container

Flixotide Nebules are presented in 2.5 ml medical grade low density polythene containers. Each nebule contains 2 ml 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 product if discoloured.

Discard unused suspension in bowl of nebuliser.

It is advisable to administer via a mouth piece.

If using a face mask, protect the skin with barrier cream, or wash face thoroughly after treatment.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/144/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th February 2015

10 DATE OF REVISION OF THE TEXT