

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Dostinex 500 microgram Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 micrograms cabergoline as the active ingredient

Excipient(s) with known effect: Each tablet also contains lactose

For the full list of excipients, see Section 6.1.

### 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from Spain:*

4 x 8 mm capsule-shaped, flat, white tablets. Scored, with a letter P on one side of the score and U on the other, on one face; and “700” with a short score in the middle of the upper and lower extremity of the tablet surface on the opposite face of the tablet. The tablet can be divided into equal doses.

### 4 CLINICAL PARTICULARS

As per PA0822/126/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0822/126/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Lactose anhydrous

Leucine

#### 6.2 Incompatibilities

Not applicable.

#### 6.3 Shelf life

The shelf life expiry date for 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

Do not store above 25°C.

Keep the bottle tightly closed in order to protect from moisture.

## **6.5 Nature and contents of container**

Type I amber glass bottles with tamper resistant screw caps and containing silica gel desiccant. Each bottle contains 8 tablets.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

LTT Pharma Limited  
Unit 18, Oxleasow Road  
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Worcestershire B98 0RE  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/108/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 28<sup>th</sup> February 2014

## **10 DATE OF REVISION OF THE TEXT**

April 2017