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.

Excipients with known effect: lactose anhydrous.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product sourced from Spain and The Netherlands:

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 halves.

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 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

Do not store above 25˚C.
Keep the bottle tightly closed in order to protect from moisture.

6.5 Nature and contents of container

Amber glass bottles with tamper resistant screw caps and containing silica gel desiccant or high-density polyethylene bottles with a child-resistant polypropylene cap which has a desiccant canister containing silica gel. Each bottle contains 8 tablets.

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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/338/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th October 2014

10 DATE OF REVISION OF THE TEXT

May 2023