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:
Each tablet also contains 75.9 mg anhydrous lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from 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

4.1 Therapeutic indications

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 bottle 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

High-density polyethylene (HDPE) bottles with child-resistant polypropylene (PP) cap with inner low-density polyethylene (LDPE) desiccant canister containing silica gel.

Each bottle contains 8 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/035/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th July 2024

10 DATE OF REVISION OF THE TEXT