# 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 anhydrous lactose.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.

Product imported from *Greece*
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. Each bottle contains 8 tablets.

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

No special requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/162/001

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

Date of first authorisation: 1st April 2021

**10 DATE OF REVISION OF THE TEXT**