Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Kemadrin 5 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains procyclidine hydrochloride 5 mg.
Excipient(s) with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets.

Product imported from Belgium:
White, round, biconvex tablets, one face with a break-line and coded KT above the breakline and 05 below the break-line, with a score line on the other face.

The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

As per PA1691/005/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1691/005/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

lactose monohydrate
sodium carboxymethyl starch type A
povidone
magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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.

6.5 Nature and contents of container

Amber glass bottles with polyethylene snap-fit closure containing 100 tablets.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/494/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th September 2022

10 DATE OF REVISION OF THE TEXT

December 2022