

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
Excipients with known effect:
Lactose Monohydrate and Sodium
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets

Product imported from Hungary

White, round, biconvex tablets, one face with a break-line and coded KT above the breakline and 05 below the breakline, 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

Magnesium Stearate
Povidone
Sodium Starch Glycolate (Type A)
Lactose Monohydrate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle label 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 bottle with a polyethylene cap containing 100 tablets, in a box.

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

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/196/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th November 2016

10 DATE OF REVISION OF THE TEXT