

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aricept 5mg film-coated tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg donepezil hydrochloride, equivalent to 4.56 mg of donepezil free base.
Excipients with known effect: lactose

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated Tablet

Product imported from the UK:

White, round, biconvex tablets embossed "ARICEPT" on one side and '5' on the other side.

4 CLINICAL PARTICULARS

As per PA0822/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Microcrystalline cellulose
Hydroxypropyl cellulose
Magnesium stearate
Hypromellose
Talc
Macrogol
Titanium dioxide (E171).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C

6.5 Nature and contents of container

Blister (PVC/Aluminium)

Pack sizes: 28 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/129/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th October 2014

10 DATE OF REVISION OF THE TEXT