

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.

Excipient: lactose monohydrate 87.17 mg per tablet.
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet

Product imported from the Czech Republic:
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
Hyprolose
Magnesium stearate

film coating

Talc
Macrogol 8000
Hypromellose
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 container and outer packaging 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

Blisters in cardboard cartons of 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

Clear Pharmacy
157-173 Roden Street
Belfast BT12 5QA
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1596/047/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd June 2011

10 DATE OF REVISION OF THE TEXT

January 2017