

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

ARICEPT 5 mg 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 with known effect: contains lactose

For the 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  
Talc  
Macrogol  
Hypromellose  
Titanium dioxide (E171)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product is 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 30°C.

#### **6.5 Nature and contents of container**

Blisters of 28 tablets contained in a carton.

#### **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**

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

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/426/001

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

Date of first authorisation: 20<sup>th</sup> January 2017

### **10 DATE OF REVISION OF THE TEXT**