

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Solian 100mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amisulpride 100 mg per tablet.

Also contains lactose monohydrate.  
For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet

*Product imported from the UK:*  
White to off-white, round flat faced breakable tablet engraved ‘AMI 100’ on one face with a breakable bar on the other face.

## 4 CLINICAL PARTICULARS

As per PA0540/158/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0540/158/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium Starch Glycolate  
Lactose Monohydrate  
Microcrystalline Cellulose  
Hypromellose  
Magnesium Stearate

### 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 carton of the product as marketed in the country of origin.

### 6.4 Special precautions for storage

No special precautions for storage.

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

Blister packs containing 60 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**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/412/003

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

Date of first authorisation: 23<sup>rd</sup> December 2016

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