

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Solian 50mg Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amisulpride 50mg per tablet.

#### Excipient(s) with known effect

Lactose monohydrate.

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Tablet

*Product imported from the United Kingdom*

White to off-white, round flat-faced tablet engraved 'AMI 50' on one face.

### 4 CLINICAL PARTICULARS

As per PA0540/158/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0540/158/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Lactose monohydrate  
Microcrystalline cellulose  
Sodium starch glycolate  
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 package of the product on the market in the country of origin.

#### 6.4 Special precautions for storage

No special precautions for storage.

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

PVC/aluminium foil 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**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/126/001

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

Date of first authorisation: 19<sup>th</sup> September 2014

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

April 2018