

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solian 50mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amisulpride 50 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 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

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

PPA0465/412/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd December 2016

10 DATE OF REVISION OF THE TEXT