

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solian 200mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amisulpride 200 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 200' on one face and with a breakable bar on the other face.

The scoreline / breakline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA 0540/158/003

5 PHARMACOLOGICAL PROPERTIES

As per PA 0540/158/003

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/412/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th May 2015

10 DATE OF REVISION OF THE TEXT