

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solian 200mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Solian 200mg tablet contains 200mg amisulpride

Also contains lactose monohydrate.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Product imported from Italy.

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 PA0540/158/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/158/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium starch glycolate (type A)
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 package of the product on the market in the country of origin.

6.4 Special precautions for storage

No special storage conditions.

6.5 Nature and contents of container

Blister pack of 30 tablets in an over labelled outer 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 precautions

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/176/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th October 2012

10 DATE OF REVISION OF THE TEXT

March 2015