

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solian 200mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 200mg amisulpride.

Excipients: 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.

4 CLINICAL PARTICULARS

As per PA 540/158/003.

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/158/003.

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 is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister strips of 10 tablets contained in an outer carton.
Pack size: 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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/129/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th December 2009

10 DATE OF REVISION OF THE TEXT

February 2015