

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solian 100mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amisulpride 100mg per tablet
Also contains lactose monohydrate.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Product imported from UK:

White to off white, round, flat-faced breakable tablets engraved with ‘AMI 100’ on one face and with a breakline on the other.
The score line / break line is only to facilitate breaking for ease of swallowing and not to divide into equal doses

4 CLINICAL PARTICULARS

As per PA0540/158/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/158/002.

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 inner and outer packaging 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

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

PPA1151/129/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th October 2013

10 DATE OF REVISION OF THE TEXT

February 2015