

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solian 50mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50mg of amisulpride.
Excipient of known effect: 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 tablets engraved with ‘AMI 50’ on one face and plain on the reverse.

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 package of the product on the market 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

Cardboard outer containing blister strips.
Pack size: 60 tablets

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/129/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th June 2014

10 DATE OF REVISION OF THE TEXT

February 2015