

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solian 100mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amisulpride 100mg per tablet.

Excipient(s) with known effect

Lactose monohydrate.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Product imported from the United Kingdom

White to off white, round flat-faced, breakable tablet engraved ‘AMI 100’ 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 PA0540/158/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/158/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Sodium starch glycolate
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 precautions for storage.

6.5 Nature and contents of container

PVC/aluminium foil 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

LTT Pharma Limited
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B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/126/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th September 2014

10 DATE OF REVISION OF THE TEXT

April 2018