

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solian 400mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amisulpride 400mg per tablet.
Also contains lactose monohydrate.

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Film coated Tablet

Product imported from the United Kingdom

A white film-coated scored oblong tablet engraved AMI 400. The scoreline/breakline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA0540/158/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/158/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Sodium starch glycolate
Hypromellose
Magnesium Stearate
Macrogol ester
Titanium dioxide (E171)

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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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/126/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th September 2014

10 DATE OF REVISION OF THE TEXT

June 2015