

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dolmatil 400 mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 400mg sulphiride.
Also contains lactose.
For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK.

White film coated stick shaped tablets with SLP 400 on one side and a break line on the other.
The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA0540/147/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/147/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium starch glycollate
Lactose
Microcrystalline cellulose
Hydroxypropylmethylcellulose
Magnesium Stearate
Sepifilm 752 white

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Supplied in blister packs of 100 (5x20) 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
Unit 18, Oxleasow Road,
East Moons Moat, Redditch,
Worcestershire B98 0RE,
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/122/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 11th July 2014

10 DATE OF REVISION OF THE TEXT

February 2015