

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dolmatil 200 mg Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 200 mg sulpiride.
Excipient: Lactose.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK:

Plain, white, round tablet with a transverse breaking line on one side and the mark 'D200' on the other. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA0540/147/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/147/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch
Lactose
Methylcellulose
Magnesium stearate
Talc
Silica

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 as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Cardboard outer containing aluminium blister strips.
Pack size: 100 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
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/183/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 18th July 2014

10 DATE OF REVISION OF THE TEXT

January 2015