

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ditropan 5 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg oxybutynin hydrochloride as the active ingredient.
Also contains Lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from UK

Pale blue circular tablet with a centre break-line on one side and marked with ‘OXB5’ on the reverse.

4 CLINICAL PARTICULARS

As per PA0540/146/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/146/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Cellulose
Calcium Stearate
Indigo Carmine (E132)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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 30° C.

6.5 Nature and contents of container

Packs contain 84 tablets in three foil blister strips of 28 tablets each.

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
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/180/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th October 2016

10 DATE OF REVISION OF THE TEXT