

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ditropan 5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Also contains lactose, anhydrous.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK:

Pale blue circular tablet with a centre break-line on one side and marked '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, anhydrous
Microcrystalline cellulose
Calcium stearate
Indigo carmine aluminium lake (E132)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer carton 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 containing 84 tablets in four foil blister strips of 21 tablets each in an over-labelled outer carton.

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

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/252/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th August 2010

10 DATE OF REVISION OF THE TEXT

October 2014