

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

LYRINEL XL 10 mg prolonged release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged release tablet contains 10 mg oxybutynin hydrochloride

Excipient(s) with known effect:

Each LYRINEL XL 10 mg prolonged release tablet contains 0.03 mg lactose.

3 PHARMACEUTICAL FORM

Prolonged release tablet.

Product imported from Greece

Round pink coloured tablet, approximately 7.5 mm in diameter, printed with "10 XL" on one side in black ink.

4 CLINICAL PARTICULARS

As per PA22612/008/002

5 PHARMACOLOGICAL PROPERTIES

As per PA22612/008/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E321)

Cellulose acetate 398-10

Hypromellose 5 cp

Polyethylene glycol 3350

Magnesium stearate

Polyethylene oxide 200K

Polyethylene oxide 2000K

Sodium chloride

Black iron oxide (E172)

Ferric oxide red (E172)

Lactose anhydrous

Film coat:

Ferric oxide red (E172)

Hypromellose 3 cp and 6 cp

Polyethylene glycol 400

Polysorbate 80

Titanium dioxide (E171)

Printing Ink:

Black iron oxide (E172)

Hypromellose 6 cp

Propylene glycol.

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 as marketed in the country of origin.

6.4 Special precautions for storage

Keep the container tightly closed in order to protect from moisture. Do not store above 25°C.

6.5 Nature and contents of container

High density polyethylene bottles with child resistant closure (polypropylene) and desiccant. Pack size 30 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

Do not remove or swallow the sachet of granules in the bottle. This contains desiccant, which keeps the tablets dry.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/486/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th December 2021

10 DATE OF REVISION OF THE TEXT

December 2021