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 of oxybutynin hydrochloride

Excipient(s) with known effect:
Each LYRINEL XL prolonged release tablet contains 0.03 mg lactose.
Each LYRINEL XL prolonged release tablet contains less than 1 mmol sodium (23 mg), and is essentially 'sodium-free'.

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Prolonged release tablet.

Product imported from Greece
Round pink coloured tablet 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 your medicine in the original package. Do not store above 25°C. Keep the container tightly closed to protect from moisture.

6.5 Nature and contents of container

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/194/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th July 2022

10 DATE OF REVISION OF THE TEXT