Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xyzal 0.5 mg/ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of oral solution contains 0.5 mg levocetirizine dihydrochloride.

Excipient(s) with known effect:
methyl parahydroxybenzoate
propyl parahydroxybenzoate
maltitol liquid
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution

Product imported from Czech Republic
Clear and colourless solution

4 CLINICAL PARTICULARS

As per PA0891/003/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0891/003/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium acetate trihydrate (for pH adjustment)
Glacial acetic acid (for pH adjustment)
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Glycerol 85%
Maltitol liquid (E965)
Saccharin sodium
Tutti frutti flavor contains:
triacetin (E1518)

benzaldehyde
orange oil
vanillin
ethyl butyrate
orange oil concentrated
isoamyl acetate
allyl hexanoate
gamma-undecalactone
citral
geraniol
citronellol
alpha tocopherol (E307)
purified water

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 on the market in the country of origin.
After first opening: 3 months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Amber glass bottle closed with a white polypropylene child-resistant closure in a cardboard box also containing a 10 ml oral syringe graduated at 0.25 ml.
Pack size: 200 ml.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne

Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/169/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th Ocotober 2017

10 DATE OF REVISION OF THE TEXT

November 2018