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
acetic acid
methyl parahydroxybenzoate (E218)
propyl parahydroxybenzoate (E216)
glycerol 85%
maltitol (E965)
saccharin sodium
Fruit flavour contains
triacetin (E1518)

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle 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

Glass bottle closed with a white 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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18
Oxleasow Road
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Redditch, Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/187/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th April 2017

10 DATE OF REVISION OF THE TEXT