Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xyzal 5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.

Excipient with known effect: lactose monohydrate

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated Tablet

Product imported from Austria, the United Kingdom, Czech Republic and the Netherlands:
White to off-white, oval, film-coated tablet with a Y logo on one side

4 CLINICAL PARTICULARS

As per PA0891/003/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0891/003/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Microcrystalline cellulose
Lactose monohydrate
Colloidal anhydrous silica
Magnesium stearate

Coating:
Hypromellose (E464)
Titanium dioxide (E 171)
Macrogol 400

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 package of the product on the market in the country of origin.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Blister packs of 28 and 30 tablets contained in an outer cardboard carton.
Not all pack sizes may be marketed.

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

PPA0465/169/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 November 2005

Date of last authorisation: 04 November 2010

10 DATE OF REVISION OF THE TEXT

January 2018