

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(s) with known effect

Lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the UK & Czech Republic

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

Microcrystalline cellulose
Lactose monohydrate
Colloidal anhydrous silica
Magnesium stearate
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 shall be 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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Cardboard outer containing blister strips. Pack size: 28 or 30.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/052/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 19th December 2007

10 DATE OF REVISION OF THE TEXT

April 2018