

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xyzal 5mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.
Excipients: lactose monohydrate
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet (tablet)

Product imported from the UK
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

Aluminium – OPA/aluminium/PVC blister
Carton containing 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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B & S Healthcare
Unit 4, Bradfield Road
Ruislip
Middlesex HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/114/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th August 2009

10 DATE OF REVISION OF THE TEXT

February 2015