Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zirtek 1 mg/ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains 1 mg cetirizine dihydrochloride.

Excipients with known effect:
- one ml of solution contains 450 mg sorbitol (solution at 70 %, non crystallizing)
- one ml of solution contains 1.35 mg methylparahydroxybenzoate
- one ml of solution contains 0.15 mg propylparahydroxybenzoate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution

Product imported from Spain
Clear and colorless liquid with slightly sweet taste and a banana flavour

4 CLINICAL PARTICULARS

As per PA0891/008/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0891/008/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol solution at 70% (non crystallizing) (E420)
Glycerol (E422)
Propylene glycol (E 1520)
Saccharin sodium
Methylparahydroxybenzoate (E218)
Propylparahydroxybenzoate (E216)
Banana flavour 54.330/A (Firmenich)
Sodium acetate
Glacial acetic acid
Purified water

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 carton of this product as marketed 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 (type III Ph. Eur.) containing volume of 200 ml, closed with a white polypropylene "child-proof" cap.

A 5 ml measuring spoon with a line at 2.5 ml is provided with the bottle.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/062/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd June 2023

10 DATE OF REVISION OF THE TEXT

September 2024