Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Clarityn 10 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg loratadine.

Excipients with known effect: contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from Greece
White to off-white, oval tablet with a score on one side and plain on the other side.
The score line of the tablet is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA1410/075/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/075/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container[1] and outer carton of the product as marketed 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

Clarityn tablets are blister packs consisting of aluminium foil with vinyl heat coating and a clear PVC film. with ten tablets per blister. Each pack contains 30 tablets on 3 blister strips.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3,
Harcourt Centre,
Harcourt Road,
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/060/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th May 2023

10 DATE OF REVISION OF THE TEXT