Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Drynol 20mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg of bilastine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the Czech Republic:
Oval biconvex scored white tablets.
The score line is only to facitlitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA0865/018/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0865/018/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

microcrystalline cellulose,
sodium starch glycolate type A (from potato starch),
colloidal anhydrous silica,
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 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

Blisters with 30 tablets in a carton.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/424/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st March 2017

10 DATE OF REVISION OF THE TEXT