Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Drynol 20 mg 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 Belgium:
Oval biconvex scored white tablets (length 10 mm, width 5 mm).
The score line is only to facilitate 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

Cellulose, microcrystalline
Sodium Starch glycolate type A (derived from potato)
Silica, colloidal anhydrous
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 blister 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

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

IMED Healthcare Ltd.,
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/263/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st August 2026

10 DATE OF REVISION OF THE TEXT