

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Telfast Allergy 120 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 120 mg of fexofenadine hydrochloride, which is equivalent to 112 mg of fexofenadine.  
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from France:*

Peach, modified capsule-shaped, film-coated tablet debossed with '012' on one side and a scripted 'e' on the other side.

## 4 CLINICAL PARTICULARS

As per PA23180/014/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23180/014/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Microcrystalline Cellulose  
Pregelatinised Maize Starch  
Croscarmellose Sodium  
Magnesium Stearate  
Hypromellose  
Povidone  
Titanium Dioxide (E171)  
Colloidal Anhydrous Silica  
Macrogol 400  
Red Iron oxide  
Yellow Iron oxide

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

### 6.4 Special precautions for storage

This medicinal product should be stored away from moisture.

**6.5 Nature and contents of container**

Carton containing blisters of 30 tablets.

**6.6 Special precautions for disposal**

No special requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/500/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 24<sup>th</sup> March 2023

**10 DATE OF REVISION OF THE TEXT**