

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Telfast 120mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 120mg of fexofenadine hydrochloride, which is equivalent to 112mg of fexofenadine.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablets

*Product imported from the UK:*

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 PA0540/078/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0540/078/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

*Tablet Core*

Microcrystalline cellulose  
Pregelatinised maize starch  
Croscarmellose sodium  
Magnesium Stearate

*Film coating*

Hypromellose  
Povidone  
Titanium dioxide (E171)  
Colloidal anhydrous silica  
Macrogol 400  
Iron oxide (E172)

### 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**

30 tablets in blisters, presented in an overlabelled outer carton

#### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/253/001

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

Date of first authorisation: 29th of October 2010

### **10 DATE OF REVISION OF THE TEXT**

August 2017