

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Telfast 180mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 180mg of fexofenadine hydrochloride, which is equivalent to 168mg of fexofenadine.

For the 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 '018' on one side and a scripted 'e' on the other side.

4 CLINICAL PARTICULARS

As per PA0540/078/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/078/003

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

PPA0465/253/002

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