

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Telfast 120mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 120 mg of fexofenadine hydrochloride (equivalent to 112 mg of fexofenadine)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-Coated Tablet.

Product imported from UK:

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

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 coat:

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 for this product shall be 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

Overlabelled cardboard outer containing blister strips. Pack size 30.

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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/080/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th September 2008

10 DATE OF REVISION OF THE TEXT

October 2014