Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Prograf 0.5 mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 0.5 mg of tacrolimus (as monohydrate).

Excipient with known effect: lactose monohydrate
The printing ink used to mark the capsule contains trace amounts of soya lecithin.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard

Product imported from Poland, Croatia and Bulgaria
Opaque light yellow hard gelatin capsules imprinted in red with "0.5 mg" and "[f] 607", containing white powder.

4 CLINICAL PARTICULARS

As per PA1241/014/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1241/014/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content:
Hypromellose
Croscarmellose sodium
Lactose monohydrate
Magnesium stearate

Capsule shell:
Titanium dioxide (E 171)
Yellow iron oxide (E 172)
Gelatine

Printing ink of capsule shell: Shellac, lecithin (soya), hydroxypropyl cellulose, simeticone, red iron oxide (E 172).

6.2 Incompatibilities

Tacrolimus is not compatible with PVC. Tubing, syringes and other equipment used to prepare or administer a suspension of Prograf capsule contents should not contain PVC.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.
After opening the aluminium wrapper: 1 year.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from moisture.
Hard capsules should be taken immediately following removal from the blister.

6.5 Nature and contents of container

Blisters with ten capsules per blister. Three blisters with a desiccant in an aluminium wrapper.
Packs of 30 hard capsules in blisters.

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

PPA0465/435/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th December 2017

10 DATE OF REVISION OF THE TEXT

December 2022