Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Prograf 5 mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 5 mg of tacrolimus (as monohydrate).

Excipient with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard

Product imported from Norway
Opaque greyish red hard gelatin capsules imprinted in white with 5 mg and [f] 657, containing white powder.

4 CLINICAL PARTICULARS

As per PA1241/014/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1241/014/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content:
Hypromellose
Croscarmellose sodium
Lactose monohydrate
Magnesium stearate

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

Printing ink of capsule shell: Shellac, titanium dioxide (E 171) and propylene glycol.

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 is the date shown on the blister and outer carton of the product as marketed 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. Five blisters with a desiccant in an aluminum wrapper.

Packs of 50x1 hard capsules in perforated unit-dose blisters.

6.6 Special precautions for disposal and other handling

Based on immunosuppressive effects of tacrolimus, inhalation or direct contact with skin or mucous membranes by the formulations for injection, powder or granule contained in tacrolimus products should be avoided during preparation. If such contact occurs, wash the skin and flush the affected eye or eyes.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/435/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd October 2026

10 DATE OF REVISION OF THE TEXT