Issue date
6 October 2022

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:

- Medical Services
- Nursing
- Pharmacy
- Transplant Units or Clinics

Expert Reference Group
Content reviewed by:
Medication Safety Expert Advisory Group

Clinical Excellence Commission

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Review date
March 2023

Change to in-use shelf-life of Prograf® (immediate-release tacrolimus) capsules

Situation

The in-use shelf-life of Prograf® (immediate-release tacrolimus) capsules once removed from the inner protective aluminium wrapper has changed from 12 months to three months. This change is in response to recent stability testing undertaken by the drug sponsor.

The change was approved by the Therapeutic Goods Administration (TGA) in December 2021 and updated in the Australian Product Information and Consumer Medicine Information in March 2022. As the drug sponsor transitions to new packs, the TGA has permitted the continued use of Prograf packs with the 12 month in-use shelf-life printed on the box. However, use must comply to the **new three month in-use shelf life**.

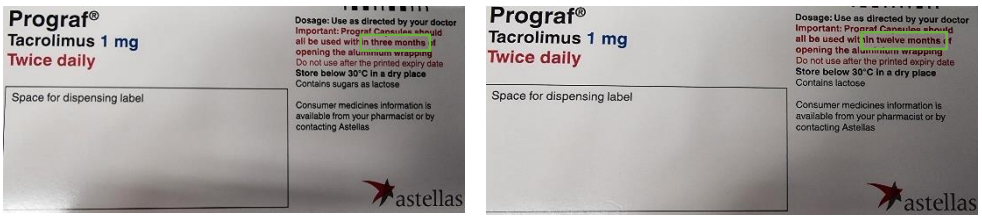
At the time of publication, no other brands of tacrolimus capsules (immediate or controlled release) are affected by this change.

Background

Prograf is indicated for use as an adjunct to liver, kidney, lung or heart allograft transplantation in adults and children.

Prograf is available in 0.5 mg, 1 mg and 5 mg capsules. They are supplied in blister strips of 10 capsules, packaged within an outer protective aluminium wrapper which reduces light exposure.

A product expiry date is the date printed on the medicine's outer packaging (box). The in-use shelf-life is the period after opening the inner protective aluminium wrapper that a medicine is considered safe and efficacious to use. Once the inner wrapper is opened, the expiry date should be clearly documented on the product's outer packaging or the dispensing label. Any medicine remaining should be discarded by the in-use shelf-life end date or the product expiry date, **whichever comes first**.



NEW PACKAGING **OLD PACKAGING**

Figure 1. Comparison of NEW and OLD packaging of Prograf® (tacrolimus immediate release) capsules

PTO

Recommendations

- Clinicians should be aware that packs of Prograf specifying use 'within twelve months of opening the aluminium wrapping' continue to be available, however use must be in accordance with the approved Product Information (i.e., use within **3 months** of opening the aluminium wrapping). Consider applying an over-label to these packs to minimise confusion.
- Ensure all patients using Prograf are educated and aware of the change to the in-use shelf-life of this medication.
- Consider the change to in-use shelf-life when dispensing Prograf® capsules via the Pharmaceutical Benefits Scheme (PBS) Section 100 High Specialised Drugs (HSD) program as some patients may require broken packs depending on their dose.

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Information to all relevant clinicians and clinical departments where Prograf capsules may be dispensed or administered.
2. Report any incidents associated with Prograf® capsules into the local incident management system (e.g., ims+) and TGA.