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Summary of Investigation Results

Tacrolimus hydrate (oral and injectable dosage forms)

March 17, 2026

Non-proprietary name

Tacrolimus hydrate (oral and injectable dosage forms)

Brand name (marketing authorization holder)

Prograf Capsules 0.5 mg, 1 mg, 5 mg, Prograf Granules 0.2 mg, 1 mg, Prograf Injection 2 mg, 5 mg, Graceptor Capsules 0.5 mg, 1 mg, 5 mg (Astellas Pharma Inc.), and the others

Japanese market launch

Prograf Capsules 0.5 mg: August 1996

Prograf Capsules 1 mg: June 1993

Prograf Capsules 5 mg: November 2000

Prograf Granules 0.2 mg, 1 mg: July 2001

Prograf Injection 2 mg: May 2011

Prograf Injection 5 mg: June 1993

Graceptor Capsules 0.5 mg, 1 mg, 5 mg: October 2008

Indications

< Prograf Capsules 0.5 mg, 1 mg >

- Prophylaxis of organ rejection in kidney, liver, heart, lung, pancreas, and small intestine transplants
- Prophylaxis of rejection and graft-versus-host disease after bone marrow transplantation
- Myasthenia gravis
- Rheumatoid arthritis (limited to cases in which conventional therapy is not sufficiently

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effective)

- Lupus nephritis (for which steroids are not sufficiently effective or are inappropriate due to adverse reactions)
- Refractory (steroid-resistant/steroid-dependent) active ulcerative colitis (limited to moderate-to-severe cases)
- Interstitial pneumonia associated with polymyositis or dermatomyositis

< Prograf Capsules 5 mg >

- Prophylaxis of organ rejection in kidney, liver, heart, lung, pancreas, and small intestine transplants
- Prophylaxis of rejection and graft-versus-host disease after bone marrow transplantation
- Refractory (steroid-resistant/steroid-dependent) active ulcerative colitis (limited to moderate-to-severe cases)

< Prograf Granules 0.2 mg, 1 mg >

- Prophylaxis of organ rejection in kidney, liver, heart, lung, pancreas, and small intestine transplants
- Prophylaxis of rejection and graft-versus-host disease after bone marrow transplantation
- Myasthenia gravis

< Prograf Injection 2 mg, 5 mg, Graceptor Capsules 0.5 mg, 1 mg, 5 mg >

- Prophylaxis of organ rejection in kidney, liver, heart, lung, pancreas, and small intestine transplants
- Prophylaxis of rejection and graft-versus-host disease after bone marrow transplantation

Summary of revisions

The results of an overseas epidemiological study should be added to the 9.5 Pregnant Women section in 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS.

Investigation results and background of the revision

The results of the overseas epidemiological study * were evaluated. This study investigated the effects of this drug on mothers and children using the data of Transplant Pregnancy



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Registry International (TPRI), which is a registry of pregnancy after organ transplantation. The data are obtained from a large-scale study concerning a limited population of pregnant women who had undergone organ transplant, and it is considered clinically useful to describe the results of this study. As a result of consultation with expert advisors regarding the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

*: A Non-interventional Post-authorization Safety Study (NI-PASS) of Outcomes Associated with the Use of Tacrolimus Around Conception, or During Pregnancy or Lactation Using Data from the Transplant Pregnancy Registry International (TPRI) (https://catalogues.ema.europa.eu/system/files/2025-09/Tacrolimus_F506-PV-0001_CSR%20draft%20v2.0%2022Nov2024-Disclosure-Redacted.pdf)

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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