Maklumat tambahan indikasi
Year 2017
Products Approved For Additional Indication (DCA 316 – 3 October 2017)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Prograf Capsules 0.5mg** [Tacrolimus 0.5 mg] 1.2 **Prograf Capsules 1mg** [Tacrolimus 1 mg]	➢ Indication: *Only for Prograf Capsules 0.5mg and 1mg* *Lupus nephritis (in a case where the effect of steroids is insufficient or administration of steroids is difficult because of their adverse reactions). For lupus nephritis, the efficacy and safety of this product for patients in an acute phase with high disease activity have not been established.* ➢ Posology: *For patients with lupus nephritis, this product should be prescribed by physicians experienced in lupus nephritis therapy.* *Only for Prograf Capsules 0.5mg and 1mg* *Lupus nephritis:* *For adults, usually, a dose of 3mg as tacrolimus is orally administered, once daily after supper. In order to avoid the development of adverse reactions in patients with lupus nephritis, it is recommended that the blood levels should be monitored monthly for 3 months after the start of tacrolimus therapy; thereafter, the blood levels approximately 12 hours after the administration should be monitored periodically, and the dosage should be adjusted. If this product does not improve the clinical signs of nephritis, such as urinary protein excretion, or the immunological findings after continuous treatment for 2 months or more, the treatment with this product should be discontinued, or the patient should be switched to another product. In cases where this product is sufficiently effective, it is recommended that the dose should be reduced to a level at which the effect can be maintained.*	**ASTELLAS PHARMA MALAYSIA SDN BHD** Suite 18.05, Level 18 Centre Point North Tower Mid Valley City Lingkaran Syed Putra 59200 Kuala Lumpur