




		EMLc	ATC codes: L04AD02
Indication	Failure or rejection of transplanted organs or tissues	ICD11 code: NE84	
INN	Tacrolimus		
Medicine type	Chemical agent		
List type	Complementary		
Formulations	Parenteral > General injections > IV: 5 mg per mL in 1 mL vial Oral > Solid: 0.5 mg (immediate-release) ; 0.75 mg (immediate-release) ; 1 mg (immediate-release) ; 2 mg (immediate-release) ; 5 mg (immediate-release) ; 0.2 mg granules for oral suspension ; 1 mg granules for oral suspension		
EML status history	First added in 2021		
Sex	All		
Age	Also recommended for children		
Therapeutic alternatives	The recommendation is for this specific medicine		
Patent information	Patents have expired in most jurisdictions Read more about patents . 		
Wikipedia	Tacrolimus 		
DrugBank	Tacrolimus 		

Expert Committee recommendation

The Expert Committee noted the unmet public health need for prevention and treatment of rejection in organ transplantation. Tacrolimus has been studied for over 25 years as an immunosuppressant specifically focused on reducing graft rejection after transplantation. Originally studied in liver transplant patients, a series of trials has expanded its use to a wide range of other types of organ transplants. Tacrolimus has been in wide clinical use for many years and it is licensed for use in children and adults in several countries. The EML currently lists azathioprine and ciclosporin as immunomodulators for use in organ transplantation. The Committee acknowledged that the available evidence suggests that tacrolimus is superior to ciclosporin with regard to graft loss and acute rejection. Based on these considerations and the overall favourable efficacy and toxicity profile of tacrolimus, the Committee recommended the inclusion of immediate-release tacrolimus on the complementary list of the EML and EMLc for use in organ transplantation. The Committee recognized that as the indication is for organ transplantation, tacrolimus would only be used in settings where organ transplantation is available and affordable. The Committee also recognized that avoiding transplant rejection and graft loss is very important in these settings given the considerable resources invested in transplantation and the scarcity of donor organs. The Committee also noted that given its narrow therapeutic window, therapeutic drug monitoring of tacrolimus blood levels is important in the context of transplantation and recommended by most international guidelines. The Committee therefore requested that therapeutic drug monitoring for tacrolimus should be evaluated for inclusion in the next edition of the WHO model list of essential in vitro diagnostics.

