



**P.17019/01/2022-PvPI**  
**Indian Pharmacopoeia Commission**  
**National Coordination Centre-Pharmacovigilance Programme of India**  
**(Ministry of Health & Family Welfare, Govt. of India)**

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**Monthly Drug Safety Alert**

The preliminary analysis of Adverse Drug Reaction (ADR) from the PvPI database reveals that the following suspected drug is associated with the ADR as given below.

**Table**

Sl. No.	Suspected Drug	Indications	Adverse Drug Reaction
1.	Tacrolimus	<ul style="list-style-type: none"><li>• For prophylaxis of transplant rejection in adult kidney or liver allograft rejection.</li><li>• Prophylaxis of transplant rejection in kidney, liver or heart allograft recipient.</li><li>• For prophylaxis of transplant rejection in liver, pancreas, lung, heart and kidney allograft recipients and treatment of allograft rejection resistant to treatment with other immuno- suppressive medicinal products.</li><li>• By nephrologists only- for the prophylaxis of organ rejection in patients receiving allogenic kidney transplant.</li><li>• For dermatologists-for treatment of patients with moderate to severe atopic dermatitis in whom the use of alternative conventional therapy is advisable.</li></ul>	Gingival Hypertrophy

Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADR associated with the use of above suspected drug. If, such reaction is encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer (<http://www.ipc.gov.in>), through Android Mobile App “**ADR PvPI**” and **PvPI Helpline No. 1800-180-3024**.