

Summary of risk management plan for Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsules

This is a summary of the risk management plan (RMP) for Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsules. The RMP details important risks of Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsules, how these risks can be minimised, and how more information will be obtained about Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsule's risks and uncertainties (missing information).

Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsule's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsules should be used.

Important new concerns or changes to the current ones will be included in updates of Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsule's RMP.

I. The medicine and what it is used for

Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsules is authorised for prophylaxis of transplant rejection in liver, kidney or heart allograft recipients and for treatment of allograft rejection (see SmPC for the full indication). It contains tacrolimus as the active substance and it is given by oral route.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsules, together with measures to minimize such risks, are outlined below.

Measures to minimise the risks identified for Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsules:

- Specific information, including warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures will constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information:

Important risks of Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsules are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsules. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

Important identified risks	Malignant neoplasms Serious infections and reactivation of pre-existing infections Medication errors resulting in under or over exposure to tacrolimus-containing medicinal products with potentially serious consequences Interaction with other medication and herbal drugs Ventricular hypertrophy Cardiomyopathies Use during pregnancy Use during lactation
Important potential risk	• None
Missing information	• None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsules.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Tacrolimus 0.5 mg, 1 mg and 5 mg Hard Capsules.