Part VI: Summary of the risk management plan

Summary of risk management plan for [Invented name] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules (Tacrolimus)

This is a summary of the risk management plan (RMP) for [Tacrolimus] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules. This RMP details important risks of [Tacrolimus] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules, how these risks can be minimised, and how more information will be obtained about [Tacrolimus] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules risks and uncertainties (missing information).

[Tacrolimus] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Tacrolimus] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules should be used.

Important new concerns or changes to the current ones will be included in updates of [Tacrolimus] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules RMP.

I. The medicine and what it is used for

[Tacrolimus] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules is authorised for the prophylaxis of transplant rejection in adult kidney or liver allograft recipients and the treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients. It contains tacrolimus as the active substance and it is given orally.

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

Important risks of [Tacrolimus] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules, together with measures to minimise such risks and the proposed studies for learning more about [Tacrolimus] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules risks, are outlined below.

Measures to minimise the risks for [Tacrolimus] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules include:

- Specific information, such as 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 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 necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of [Tacrolimus] 0.5mg, 1mg, 3mg & 5mg prolonged release 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] 0.5mg, 1mg, 3mg & 5mg prolonged release 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).

List of important risks and missing information	
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 risks	• 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] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules.

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

There are no studies required for [Tacrolimus] 0.5mg, 1mg, 3mg & 5mg prolonged release hard capsules.