13 Part VI: Summary of the risk management plan for Mycophenolate mofetil, 250 mg, Hard capsule and 500 mg, Film-coated tablet

This is a summary of the risk management plan (RMP) for mycophenolate mofetil, 250 mg, hard capsule and 500 mg, film-coated tablet. The RMP details important risks of mycophenolate mofetil, hard capsule and film-coated tablet, how these risks can be minimized, and how more information will be obtained about mycophenolate mofetil hard capsule and filmcoated tablet's risks and uncertainties (missing information).

Mycophenolate mofetil, hard capsule and film-coated tablet's summary of product characteristics (SmPCs) and its package leaflet give essential information to healthcare professionals and patients on how mycophenolate mofetil, hard capsule and film-coated tablet should be used.

Important new concerns or changes to the current ones will be included in updates of mycophenolate mofetil, hard capsule and film-coated tablet's RMP.

13.1 Part VI: I. The medicine and what it is used for

Mycophenolate mofetil, hard capsule and film coated tablet are authorized for:

Mycophenolate mofetil is indicated in combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants.

It contains mycophenolate mofetil as the active substance and it is given orally as hard capsule and film-coated tablet.

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of mycophenolate mofetil, hard capsule and film-coated tablet, together with measures to minimize such risks and the proposed studies for learning more about mycophenolate mofetil hard capsule and film-coated tablet's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- 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 authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In the case of mycophenolate mofetil hard capsules and film-coated tablets, these measures are supplemented with *additional risk minimization measures* mentioned under relevant important risks below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report (PSUR) assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of mycophenolate mofetil hard capsule and film-coated tablet are risks that need special risk management activities to further investigate or minimize 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 mycophenolate mofetil. 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	Bone marrow depression resulting in cytopenias and associated infections or hemorrhages
	Gastrointestinal disorders including ulceration and hemorrhage
	Hypersensitivity
	Drug-drug interaction (DDI) -- Drugs that interfere with enterohepatic recirculation and may lead to reduced efficacy of mycophenolate mofetil
	Adverse pregnancy outcomes
	Lymphomas and other malignancies, particularly of the skin
Important potential risks	Exacerbation of hereditary deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT)
	DDI – Risk of activation of live vaccines
	DDI – Lack of effect of any vaccination
	DDI – Potential interaction with azathioprine leading to increased bone marrow suppression
Missing information	None

13.2.2 Part VI – II.B: Summary of important risks

Table 13-2 Important identified risk: Adverse pregnancy outcomes

Risk minimization measures	**Routine risk minimization measures:** SmPC sections 4.3, 4.4, 4.6; PL sections 2 **Legal status:** Prescription only **Additional risk minimization measures:** Education materials: Guide for Healthcare Professionals (HCPs) and Guide for patients

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligations of mycophenolate mofetil hard capsule and film-coated tablet.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for mycophenolate mofetil hard capsule and film-coated tablet.