PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Mycophenolate Mofetil 500 mg film-coated tablet and Mycophenolate Mofetil 250 mg capsules (mycophenolate mofetil)

This is a summary of the risk management plan (RMP) for Mycophenolate Mofetil 500 mg film-coated tablets and Mycophenolate Mofetil 250 mg capsules. The RMP details important risks of Mycophenolate Mofetil 500 mg film-coated tablet and Mycophenolate Mofetil 250 mg capsules, how these risks can be minimised, and how more information will be obtained about Mycophenolate Mofetil 500 mg film-coated tablet and Mycophenolate Mofetil 250 mg capsules's risks and uncertainties (missing information).

Mycophenolate Mofetil 500 mg film-coated tablets and Mycophenolate Mofetil 250 mg capsules's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Mycophenolate Mofetil 500 mg film-coated tablet and Mycophenolate Mofetil 250 mg capsules should be used.

I. The medicine and what it is used for

Mycophenolate Mofetil 500 mg film-coated tablet and Mycophenolate Mofetil 250 mg capsules is authorised in combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants (see SmPC for the full indication). It contains mycophenolate mofetil 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 Mycophenolate Mofetil 500 mg film-coated tablet and Mycophenolate Mofetil 250 mg capsules, together with measures to minimize such risks Mycophenolate Mofetil 500 mg film-coated tablet and Mycophenolate Mofetil 250 mg capsules's risks, are outlined below.

Measures to minimise the risks identified for Mycophenolate Mofetil are:

- Specific information, including warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Prescription only medicine.

Together, these measures will constitute routine risk minimisation measures.

In the case of Mycophenolate Mofetil 500 mg film-coated tablet and Mycophenolate Mofetil 250 mg capsules, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.
If important information that may affect the safe use of Mycophenolate Mofetil 500 mg film-coated tablet and Mycophenolate Mofetil 250 mg capsules is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information:

Important risks of Mycophenolate Mofetil 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 Mycophenolate Mofetil 500 mg film-coated tablet and Mycophenolate Mofetil 250 mg 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	• Hypersensitivity • Teratogenic effects (spontaneous abortion and congenital malformations) • Serious infections including viral reactivation • Bone marrow suppression (leukopenia, thrombocytopenia, anaemia, pancytopenia), and associated haemorrhage/bleeding • Pure red cell aplasia (PRCA) • Bronchiectasis • Hypogammaglobulinaemia • Digestive system adverse events, including gastrointestinal tract ulceration, haemorrhage and perforation • Drug interactions with drugs when mycophenolate mofetil is concomitantly administered with drugs that interfere with enterohepatic recirculation • Convulsions • Hepatitis • Renal impairment • Toxicity in renal transplant patients with severe chronic renal impairment • Pancreatitis • Lymphomas and other malignancies, particularly of the skin • Exacerbations of rare hereditary deficiency of hypoxanthine guanine phosphoribosyl transferase (HGPRT)
Important potential risks	• Risk of infection with live vaccines

	• Reduced effectiveness of vaccines • Potentially reduced mycophenolate mofetil efficacy when mycophenolate mofetil is concomitantly administered with rifampicin • Interstitial lung disease and pulmonary fibrosis • Increased risk of certain infections, possibly gastrointestinal haemorrhage and pulmonary edema in elderly population • Use in cardiac or hepatic transplant patients with severe chronic renal impairment • Use in cardiac transplant patients with severe hepatic parenchymal disease • Use in paediatric cardiac or hepatic transplant patients
Missing information	• Use in paediatric population < 2 years in renal transplant • Treatment with mycophenolate mofetil during hepatic transplant rejection

II.B Summary of important risks

Important identified risks: Teratogenic effects (spontaneous abortion and congenital malformations)	
Risk minimisation measures	Routine risk minimisation measures: *Wording in sections 4.4 and 4.6 of the SmPC* *Wording in section 2 of the PIL* Other routine risk minimisation measures beyond the Product Information: Prescription only medicine Additional risk minimisation measures: *Educational materials for healthcare providers and patients*

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 Mycophenolate Mofetil 500 mg film-coated tablet and Mycophenolate Mofetil 250 mg capsules.

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

There are no studies required for Mycophenolate Mofetil 500 mg film-coated tablet and Mycophenolate Mofetil 250 mg capsules.