# 7 Part VI: Summary of the risk management plan (RMP) Mycophenolate mofetil, 250 mg Capsule, hard, 500 mg film-coated tablets

This is a summary of the RMP for Mycophenolate mofetil. The RMP details important risks of mycophenolate mofetil, how these risks can be minimized, and how more information will be obtained about mycophenolate mofetil's risks and uncertainties (missing information).

Mycophenolate mofetil summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how mycophenolate mofetil should be used.

Important new concerns or changes to the current ones will be included in updates of mycophenolate mofetil RMP.

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

Mycophenolate mofetil is indicated in combination (used together) with ciclosporin and corticosteroids for preventing your body from rejecting a transplanted organ (kidney, heart or liver). It contains mycophenolate mofetil as the active substance and it is given orally

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

Important risks of mycophenolate mofetil, together with measures to minimize such risks and the proposed studies for learning more about rmycophenolate mofetil'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 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 minimize its risks.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report (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 is not yet available, it is listed under ‘missing information’ below.

### 7.2.1 Part VI – 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 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 7-1 List of important risks and missing information**

| **List of important risks and missing information** | |
|---|---|
| Important identified risks | Bone marrow suppression (leukopenia, thrombocytopenia, anemia, pancytopenia), and associated hemorrhage/bleeding |
| | Pure red cell aplasia (PRCA) |
| | Serious infections including viral reactivation |
| | Digestive system adverse events, including gastrointestinal tract ulceration, hemorrhage and perforation |
| | Hypersensitivity |
| | Drug interactions with drugs when MMF is concomitantly administered with drugs that interfere with enterohepatic recirculation |
| | Convulsions |
| | Hepatitis |
| | Renal impairment |
| | Toxicity in renal transplant patients with severe chronic renal impairment |
| | Teratogenic effects (spontaneous abortion and congenital malformations in women) |
| Important potential risks | Teratogenic effects (spontaneous abortion and congenital malformations in men) |
| | Lymphomas and other malignancies, particularly of the skin |
| | Exacerbation of rare hereditary deficiency of hypoxanthine-guanine phosphoribosyl-transferase |
| | Risk of infection with live vaccines |
| | Reduced effectiveness of vaccines |
| | Potentially reduced MMF-efficacy when MMF is concomitantly administered with rifampicin |
| | Interstitial lung disease and pulmonary fibrosis |
| | Increased risk of certain infections, possibly gastrointestinal hemorrhage and pulmonary edema in elderly population |
| Missing information | Use in cardiac or hepatic transplant patients with severe chronic renal impairment |
| | Use in cardiac transplant patients with severe hepatic parenchymal disease |
| | Use in pediatric cardiac or hepatic transplant patients |

| List of important risks and missing information | |
|---|---|
| | Use in pediatric population < 2 years in renal transplant |
| | Treatment with MMF during hepatic transplant rejection |

### 7.2.2 Part VI – II.B: Summary of important risks

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

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

#### 7.2.3.1 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.

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

There are no studies required for mycophenolate mofetil.