Summary of risk management plan for Mycophenolic acid Tillomed 180 mg & 360 mg gastroresistant tablets:

This is a summary of the risk management plan (RMP) for Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets. The RMP details important risks of Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets, how these risks can be minimised, and how more information will be obtained about Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets' risks and uncertainties (missing information).

Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets' summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablet's RMP.

I. The medicine and what it is used for

Mycophenolic acid Tillomed 180 mg &360 mg gastro-resistant tablet is authorised in combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection after allogeneic renal transplants in adult patients.

It contains mycophenolic acid (as mycophenolate sodium) 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 Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets, together with measures to minimise such risks and the proposed studies for learning more about Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets' risks, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and HCPs;
- 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 the case of Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets, 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 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 Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets 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 Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets. 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).

Summary of safety concerns	
Important identified risks	• Hypersensitivity • Spontaneous abortion and congenital malformations in women (maternal exposure) • Bone marrow depression, associated infections and hemorrhages • Drug-drug interactions: drugs interfering with enterohepatic circulation • Gastrointestinal disorders including ulceration and haemorrhage
Important potential risks	• Carcinogenicity
Summary of safety concerns	
	• Genotoxicity • Increase in vaccination related disease • Lack of effect of vaccinations • Off-label use

	• Spontaneous abortion and congenital malformations in men (paternal exposure)
Missing information	• Use in lactation • Use in paediatric patients

II.B Summary of important risks

Spontaneous abortion and congenital malformations in women (maternal exposure)	
Risk minimization measures	**Routine risk minimization measures:** • SmPC sections 4.3, 4.4, 4.6, 4.8, 5.3 • PIL sections 2 • Information on recommendations like two negative pregnancy tests, and use of at least one form of reliable contraception method and preference for two complementary forms of contraception simultaneously to minimise the potential for contraceptive failure and unintended pregnancy in women with childbearing potential are provided in SmPC sections 4.4 and 4.6 and PIL section 2. • Information on recommendations to use reliable contraception by sexually active male patients or their female partners during treatment of the male patient and for at least 90 days after cessation of mycophenolate sodium is provided in SmPC section 4.6 and PIL section 2. • Medicinal product subject to restricted medical prescription (Treatment should be initiated and maintained by appropriately qualified transplant specialists) **Additional risk minimization measures:** Educational materials in the form of: • Patient guide • Guide for healthcare professionals **Additional pharmacovigilance activities:**
	• Questionnaires for HCPs and patients reporting exposure during pregnancy.

Spontaneous abortion and congenital malformations in men (paternal exposure)

Risk minimization measures	**Routine risk minimization measures:** • SmPC sections 4.4, 4.6 • PIL section 2 • Information on recommendations to use reliable contraception by sexually active male patients or their female partners during treatment of the male patient and for at least 90 days after cessation of mycophenolate sodium is provided in SmPC section 4.6 and PIL section 2. • Medicinal product subject to restricted medical prescription (Treatment should be initiated and maintained by appropriately qualified transplant specialists) **Additional risk minimization measures:** Educational materials in the form of: • Patient guide • Guide for healthcare professionals **Additional pharmacovigilance activities:** • Questionnaires for HCPs and patients reporting exposure during pregnancy

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 Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets.

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

There are no studies required for Mycophenolic acid Tillomed 180 mg & 360 mg gastro-resistant tablets