

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Acido Folico Mylan (folic acid)

This is a summary of the risk management plan (RMP) for Acido Folico Mylan. The RMP details important risks of folic acid, how these risks can be minimised, and how more information will be obtained about folic acid's risks and uncertainties (missing information).

Acido Folico Mylan's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCP) and patients on how it should be used.

Important new concerns or changes to the current ones will be included in updates of Acido Folico Mylan's RMP.

I. The Medicine and What it is Used For

Acido Folico Mylan is authorised for the treatment of:

- Prophylaxis of drug-induced folate deficiency, such as caused by administration of phenytoin, phenobarbital and primidone.
- Prevention of neural tube defects of the fetus in women who are planning a pregnancy and for whom the risk is known.

It contains folic acid as the active substance, and it is given orally (by mouth).

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Acido Folico Mylan, together with measures to minimise such risks and the proposed studies for learning more about Acido Folico Mylan's 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 public (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 events is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of Important Risks and Missing Information

Important risks of Acido Folico Mylan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a

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link with the use of Acido Folico Mylan. 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/use in special patient populations etc.);

Table 5: Part VI.1- Summary of safety concerns

List of Important Risks and Missing Information	
Important Identified Risks	None
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 Acido Folico Mylan.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Acido Folico Mylan.