Folic acid Vitabalans 1mg and 5 mg tablets

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PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

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

Folic acid Vitabalans' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Folic acid Vitabalans should be used.

I. The medicine and what it is used for

Folic acid Vitabalans is authorised for:

Treatment of folate deficiency, also folate deficiency states confirmed by blood test including vitamin B12 status. Usage during treatment with drugs that inhibit folate absorption or folate metabolism such as methotrexate. For the prevention of neural tube defects in the foetus for women planning a pregnancy (see SmPC for the full indication). It contains folic acid as the active substance and it is given by oral route of administration.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Folic Acid Vitabalans, together with measures to minimise such risks and the proposed studies for learning more about Folic acid Vitabalans' 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 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 minimise its risks.

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

II.A List of important risks and missing information

Important risks of Folic acid Vitabalans 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 folic acid. 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);

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

There are no important identified or potential risks or missing information to summarise.

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 Folic acid Vitabalans.

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

There are no studies required for Folic acid Vitabalans.