

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR FOLAVIT 1 MG TABLETS (FOLIC ACID)

This is a summary of the risk management plan (RMP) for Folavit 1 mg tablets. The RMP details important risks of Folavit 1 mg tablets, how these risks can be minimised, and how more

information will be obtained about Folavit 1 mg tablets's risks and uncertainties (missing information).

Folavit 1 mg tablets's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Folavit 1 mg tablets should be used.

I. THE MEDICINE AND WHAT IT IS USED FOR

Folavit 1 mg tablets is authorised for

- Reduction of side effects in patients receiving low-dose methotrexate therapy for rheumatoid arthritis, psoriasis and inflammatory bowel disease.
- Prevention or treatment of folate deficiency, which may cause macrocytic anemia.
- Prevention of neural tube defects.

See SmPC for the full indication.

It contains folic acid as the active substance and it is given by mouth.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of Folavit 1 mg tablets, together with measures to minimise such risks and the proposed studies for learning more about Folavit 1 mg tablets'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 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.

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.

II.A. LIST OF IMPORTANT RISKS AND MISSING INFORMATION

Important risks of Folavit 1 mg 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 Folavit 1 mg 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).

List of important risks and missing information	
Important identified risks	Not applicable
Important potential risks	Not applicable
Missing information	Not applicable

II.B. SUMMARY OF IMPORTANT RISKS

Not applicable.

SUMMARY OF RISK MANAGEMENT PLAN FOR FOLAVIT 5 MG TABLETS (FOLIC ACID)

This is a summary of the risk management plan (RMP) for Folavit 5 mg tablets. The RMP details important risks of Folavit 5 mg tablets, how these risks can be minimised, and how more information will be obtained about Folavit 5 mg tablets’ risks and uncertainties (missing information).

Folavit 1mg tablets's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Folavit 5 mg tablets should be used.

I. THE MEDICINE AND WHAT IT IS USED FOR

Folavit 5 mg tablets is authorised for

- Reduction of side effects in patients receiving low-dose methotrexate therapy for rheumatoid arthritis, psoriasis and inflammatory bowel disease.
- Prevention or treatment of folate deficiency, which may cause macrocytic anemia.
- Prevention of neural tube defects in women at high risk.

See SmPC for the full indication.

It contains folic acid as the active substance and it is given by mouth.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of Folavit 5 mg tablets, together with measures to minimise such risks and the proposed studies for learning more about Folavit 5 mg tablets'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 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.

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.

II.A. LIST OF IMPORTANT RISKS AND MISSING INFORMATION

Important risks of Folavit 5 mg 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 Folavit 5 mg 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).

List of important risks and missing information	
Important identified risks	Not applicable
Important potential risks	Not applicable
Missing information	Not applicable

II.B. SUMMARY OF IMPORTANT RISKS

Not applicable.