Souhrn plánu řízení rizik podle § 99 odst. 8 písm. a) zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů (1)

Folic Acid Litcon Pharma 5 mg tablety

Administrativní informace:

Léčivá látka/látky	Hydrát kyseliny listové
Léková forma/formy	Tableta
Síla/síly	5 mg
Držitel rozhodnutí o registraci	LITcon Pharma SE
Registrační číslo/čísla	12/425/21-C
Verze a datum plánu řízení rizik	1.0, 28.01.2026

Následující výňatek z plánu řízení rizik (RMP) výše uvedeného léčivého přípravku/léčivých přípravků je souhrnem podstatných informací uvedených ve zmíněném RMP. RMP popisuje opatření, která mají být přijata, aby bylo zajištěno, že tento léčivý přípravek/tyto léčivé přípravky budou používány co nejbezpečněji. Souhrn RMP je potřeba číst spolu se schváleným souhrnem údajů o přípravku/přípravcích a příbalovou informací.

Tento souhrn RMP připravil Státní ústav pro kontrolu léčiv za účelem splnění své zákonné povinnosti týkající se transparentnosti vůči veřejnosti.

1) Zákon č. 378/2007 Sb., o léčivech, ve znění pozdějších předpisů

Summary of risk management plan for Folic Acid Litcon Pharma 5 mg tablety

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

Folic Acid Litcon Pharma 5 mg tablety's summary of product characteristics and its package leaflet give essential information to healthcare professionals and patients on how Folic Acid Litcon Pharma 5 mg tablety should be used.

I. The medicine and what it is used for

Folic Acid Litcon Pharma 5 mg tablety is authorised for:

- Treatment of megaloblastic anemia due to folate deficiency, confirmed by laboratory tests including vitamin B12 status (see section 4.4 of SmPC).
- Prevention and treatment of folic acid deficiency in women at high risk of neural tube defects in the embryo during the four weeks before conception and the first trimester of pregnancy.

It contains folic acid as the active substance and intended for oral use.

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

Important risks of Folic Acid Litcon Pharma 5 mg tablety together with measures to minimise such risks and the proposed studies for learning more about Folic Acid Litcon Pharma 5 mg tablety'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 a 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, 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 Folic Acid Litcon Pharma 5 mg tablety 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 Litcon Pharma 5 mg tablety. 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

Safety profile of Folic Acid Litcon Pharma 5 mg tablety is adequately described in the product information and well-known to the healthcare professionals. No safety concerns have been identified.

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 Litcon Pharma 5 mg tablety.

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

There are no studies required for Folic Acid Litcon Pharma 5 mg tablety.