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)

Auruven 50 mg tvrdé tobolky, Auruven 100 mg tvrdé tobolky

Administrativní informace:

Léčivá látka/látky	makrokrystalický nitrofurantoin
Léková forma/formy	tvrdé tobolky
Síla/síly	50 mg, 100 mg
Držitel rozhodnutí o registraci	LITcon Pharma SE
Registrační číslo/čísla	15/070/24-C, 15/071/24-C
Verze a datum plánu řízení rizik	RMP 1.0, 25.3.2025

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 Auruven 50 mg tvrdé tobolky and Auruven 100 mg tvrdé tobolky (makrokrystalický nitrofurantoin)

This is a summary of the risk management plan (RMP) for Auruven 50 mg tvrdé tobolky and Auruven 100 mg tvrdé tobolky (hereinafter will be collectively referred to in this document as "Auruven"). The RMP details important risks of Auruven, how these risks can be minimised, and how more information will be obtained about Auruven risks and uncertainties (missing information).

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

Important new concerns will be included in updates of Auruven's RMP.

I. The medicine and what it is used for

Auruven is authorised for use in adults and adolescents from 12 years of age for the treatment of acute or prophylaxis of recurrent uncomplicated lower urinary tract infections caused by microorganisms sensitive to nitrofurantoin (see SmPC for the full indication).

It contains nitrofurantoin as the active substance and is administered orally.

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

Important risks of Auruven, together with measures to minimise such risks and the proposed studies for learning more about Auruven 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 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 Auruven 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 Auruven. 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

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 Auruven.

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

There are no studies required for Auruven.