SUMMARY OF RISK MANAGEMENT PLAN FOR URISPAS (FLAVOXATE HYDROCHLORIDE)- VERSION 2.0

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

Urispas's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Urispas should be used.

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

I. The medicine and what it is used for

Urispas is authorized for the symptomatic relief of urinary tract symptoms, such as dysuria, urgency, nocturia, vesical supra-pubic pain, frequency and incontinence, as may occur in different urological conditions (see local SmPC for the full indication). Each film coated tablet contains flavoxate hydrochloride an active ingredient and taken orally.

II. Risks associated with the medicine and activities to minimize or further characterize the risks.

Important risks of Urispas, together with measures to minimize such risks and the proposed studies for learning more about Urispas's risks, are outlined below.

Measures to minimize 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 authorized 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 minimize its risks.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed so that immediate action can be taken as necessary.

Together, these measures constitute routine risk minimization measures.

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II.A List of important risks and missing information

None.

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Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

None

II.C Post-authorization development plan

No post-authorization study is planned for this product.

II.C.1 Studies which are conditions of the marketing authorization.

No studies are conditions of the marketing authorization or specific obligations of Urispas.

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

Not applicable.