

**Clotrimazole Vaginal Dosage Forms
Core Risk Management Plan
Part VI: Summary of the risk management plan**

**PART VI
Summary of the Risk Management Plan**

Active substance(s) (INN or common name):	Clotrimazole
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Medicinal products to which this RMP refers:	Clotrimazole is an active ingredient in various dosage forms intended for intravaginal use. All such formulations are referred to in this RMP.
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Name of Marketing Authorization Holder or Applicant:	Bayer AG
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Data lock point for this module 30 APR 2023

Version number of RMP when this module was last updated 6.1

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Summary of Risk Management Plan for Clotrimazole Vaginal Dosage Forms

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

Clotrimazole's vaginal dosage forms summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how clotrimazole should be used.

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.

I. The medicine and what it is used for

Clotrimazole vaginal dosage forms are indicated for the treatment of infections of the genital region (vaginitis) caused by fungi (usually *Candida*), and superinfections caused by clotrimazole-sensitive bacteria. The cream dosage form also treats infections of the labia and adjacent areas as well as inflammation of the glans and prepuce of the sexual partner caused by yeast fungi (*candidal vulvitis* and *candidal balanitis*). Clotrimazole vaginal dosage forms are available as intravaginal creams, tablet/pessaries, and capsules and external creams with different strengths and duration of treatment.

II. Risks Associated with the Medicine and Activities to Minimise or further Characterise the Risks

Important risks of Clotrimazole vaginal dosage forms, together with measures to minimise such risks and the proposed studies for learning more about clotrimazole'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 patient (e.g. with or without prescription) can help to minimize its risks.

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

II.A List of important risks and missing information

Important risks of clotrimazole vaginal dosage forms are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. 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 clotrimazole. 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

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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).

Table Part VI-1: List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable

II.C Post-authorization development plan

There are no studies which are conditions of the marketing authorization or specific obligation for clotrimazole.

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

There are no studies required for clotrimazole vaginal dosage forms.

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

There are no studies required for clotrimazole vaginal dosage forms.