

Part VI: Summary of the risk management plan

Summary of risk management plan for Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten (Nystatin)

This is a summary of the risk management plan (RMP) for Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten. The RMP details important risks of Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten, how these risks can be minimised, and how more information will be obtained about Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten's risks and uncertainties (missing information).

Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten should be used.

Important new concerns or changes to the current ones will be included in updates of Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten's RMP.

I. The medicine and what it is used for

Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten is authorised for the treatment of vulvovaginal candidiasis in adults (see SmPC for the full indication). It contains nystatin as the active substance and it is given by ointment (1 g ointment contains 100 000 IU Nystatin) and vaginal tablets (1 vaginal tablet contains 100 000 IU nystatin).

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

Important risks of Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten together with measures to minimise such risks and the proposed studies for learning more about Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten'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, 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 Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten 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 Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten. 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	<ul style="list-style-type: none">• None
Important potential risks	<ul style="list-style-type: none">• None
Missing information	<ul style="list-style-type: none">• None

II.B Summary of important risks

Not applicable, as no important risks and missing information are 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 Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten.

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

There are no studies required for Biofanal Kombi 100000 I.E./g Salbe und 100000 I.E. Vaginaltabletten.