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)

Pelmivekal 10 mg/g krém

Administrativní informace:

Léčivá látka/látky	klotrimazol
Léková forma/formy	krém
Síla/síly	10 mg/g
Držitel rozhodnutí o registraci	Dr. Müller Pharma s.r.o.
Registrační číslo/čísla	26/545/24-C
Verze a datum plánu řízení rizik	verze 1.0, 23.02.2026

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 Pelmivekal (clotrimazole)

This is a summary of the risk management plan (RMP) for Pelmivekal 10 mg/g cream. The RMP details important risks of Pelmivekal 10 mg/g cream, how these risks can be minimised, and how more information will be obtained about Pelmivekal's risks and uncertainties (missing information).

Pelmivekal 10 mg/g cream's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pelmivekal 10 mg/g cream should be used.

I. The medicine and what it is used for

Pelmivekal 10 mg/g cream is broad spectrum antifungal agent, intended only for local application. It is used for the treatment of inflammations caused by fungal microorganisms, molds and yeast, primarily Candida species.

Pelmivekal 10 mg/g cream is used for local treatment of fungal skin infections with various localization: tinea pedis, tinea manuum, tinea corporis, tinea inguinalis, pityriasis versicolor (caused by Malassezia furfur), erythrasma (Corynebacterium minutissimum), skin infections caused by bacteria sensitive to this medicinal product, seborrheic dermatitis only with participation of mentioned pathogens.

Pelmivekal 10 mg/g cream is also used in the treatment of vulvitis in women and balanitis in men (caused primarily by Candida species).

It contains clotrimazole as the active substance and it is applied on skin in the form of cream.

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

Important risks of Pelmivekal 10 mg/g cream, together with measures to minimise such risks and the proposed studies for learning more about Pelmivekal 10 mg/g cream'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 Pelmivekal 10 mg/g cream 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 Pelmivekal 10 mg/g cream. 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 Pelmivekal 10 mg/g cream.

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

There are no studies required for Pelmivekal 10 mg/g cream.