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)

Sildenafil Medreg 50 mg potahované tablety

Sildenafil Medreg 100 mg potahované tablety

Administrativní informace:

Léčivá látka/látky	sildenafil citrát
Léková forma/formy	potahované tablety
Síla/síly	50 mg, 100 mg
Držitel rozhodnutí o registraci	Medreg s r.o. Praha
Registrační číslo/čísla	83/388/23-C, 83/184/15-C
Verze a datum plánu řízení rizik	Verze 3.0 , 03.09.2025

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 Sildenafil Medreg 50,100 mg film-coated tablets (sildenafil citrate)

This is a summary of the risk management plan (RMP) for Sildenafil Medreg 50,100 mg film-coated tablets (hereinafter referred to as Sildenafil Medreg). The RMP details important risks of Sildenafil

Medreg, and how more information will be obtained about Sildenafil Medreg 's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Sildenafil Medreg´s RMP.

I. The medicine and what it is used for

Sildenafil Medreg is authorised for erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance in adult men. It contains sildenafil citrate as the active substance, and it is given orally.

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

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

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

There are no studies required for Sildenafil Medreg.