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)

Tadalafil Rontis 5 mg žvýkací tablety

Tadalafil Rontis 10 mg žvýkací tablety

Tadalafil Rontis 20 mg žvýkací tablety

Administrativní informace:

Léčivá látka/látky	tadalafil
Léková forma/formy	Žvýkací tableta
Síla/síly	5 mg, 10 mg, 20 mg
Držitel rozhodnutí o registraci	Rontis Hellas Medical and Pharmaceutical Products S.A.
Registrační číslo/čísla	83/659/24-C, 83/660/24-C, 83/661/24-C
Verze a datum plánu řízení rizik	verze 1.0, 2.10.2025

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 Tadalafil Rontis (Tadalafil)

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

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

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

I The medicine and what it is used for

Tadalafil 5 mg, 10 mg and 20 mg chewable tablets:

Treatment of erectile dysfunction in adult males. In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required.

Tadalafil 5 mg chewable tablets:

Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males. Tadalafil Rontis is not indicated for use by women.

Tadalafil 20 mg chewable tablets:

Tadalafil is indicated in adults for the treatment of pulmonary arterial hypertension (PAH) classified as WHO functional class II and III, to improve exercise capacity.

Efficacy has been shown in idiopathic PAH (IPAH) and in PAH related to collagen vascular disease.

Tadalafil is indicated in paediatric patients aged 2 years and above for the treatment of pulmonary arterial hypertension (PAH) classified as WHO functional class II and III.

It contains tadalafil as the active substance, and it is given by oral route of administration of 5 mg, 10 mg and 20 mg chewable tablets.

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

Important risks of Tadalafil Rontis together with measures to minimise such risks and the proposed studies for learning more about tadalafil's risks, are outlined below. EU RMP – Tadalafil, 5 mg, 10 mg and 20 mg chewable tablets.

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 Tadalafil Rontis are risks that need special risk management activities to further investigate or minimise 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 Tadalafil Rontis. 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).

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 Tadalafil Rontis.

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

There are no studies required for Tadalafil Rontis.