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)

Teriflunomide Koanaa 7 mg potahované tablety

Teriflunomide Koanaa 14 mg potahované tablety

Administrativní informace:

Léčivá látka/látky	teriflunomid
Léková forma/formy	potahované tablety
Síla/síly	7 mg, 14 mg
Držitel rozhodnutí o registraci	Koanaa Healthcare GmbH
Registrační číslo/čísla	59/546/21-C, 59/547/21-C
Verze a datum plánu řízení rizik	verze 0.5, 14.04.2025

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 Teriflunomide Koanaa 7mg and 14 mg film - coated tablets (Teriflunomide)

This is a summary of the risk management plan (RMP) for Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets. The RMP details important risks of teriflunomide, how these risks can be minimised, and how more information will be obtained about Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets' risks and uncertainties (missing information).

Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets' RMP.

I. The medicine and what it is used for

Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets is indicated for the treatment of adult and pediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (see SmPC for the full indication). It contains active substance teriflunomide and it is given by oral route.

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

Important risks of Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets' 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 SmPC and PIL 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 the case of Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets, these measures are supplemented with additional risk minimization measures mentioned under relevant sections of important risks, outlined in the next sections.

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.

If important information that may affect the safe use of Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets is not yet available, it is listed under "missing information".

II.A List of important risks and missing information

Important risks of Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or 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 Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets. 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 and potential risks, together with missing information, are summarised in the following Table:

List of important risks and missing information	
Important Identified Risks	Hepatic effects Hypertension Hematologic effects Infections Acute pancreatitis
Important Potential Risks	Teratogenicity Serious opportunistic infections, including PML
Missing information	None

PML: Progressive Multifocal Leukoencephalopathy.

II.B Summary of important risks

Important identified risk: Hepatic effects	
Risk minimization measures	Routine risk minimization measures: SmPC: Sections 4.2, 4.3, 4.4 and 4.8. PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU). Additional risk minimization measures: • Healthcare professional guide • Patient card
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None

Important identified risk: Hypertension	
Risk minimization measures	Routine risk minimization measures: SmPC: Sections 4.4 and 4.8. PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU). Additional risk minimization measures: Educational Material (HCP guide and Patient card)
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None

Important identified risk: Hematologic effects	
Risk minimization measures	Routine risk minimization measures: SmPC: Sections 4.3, 4.4 and 4.8. PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU). Additional risk minimization measures: Educational Material (HCP guide and Patient card)
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None

Important identified risk: Infections	
Risk minimization measures	Routine risk minimization measures: SmPC: Sections 4.3, 4.4 and 4.8. PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU). Additional risk minimization measures: Educational Material (HCP guide and Patient card)
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None

Important identified risk: Acute pancreatitis	
Risk minimization measures	Routine risk minimization measures: SmPC: Sections 4.4 and 4.8. PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU). Additional risk minimization measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None

Important identified risk: Teratogenicity	
Risk minimization measures	Routine risk minimization measures: SmPC: Sections 4.3 and 4.6. PIL: Sections 2 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU). Additional risk minimization measures: Educational Material (HCP guide and Patient card)
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None

Important identified risk: Serious opportunistic infections, including PML	
Risk minimization measures	Routine risk minimization measures: SmPC: Sections 4.3, 4.4 and 4.8. PIL: Sections 2 and 4 Legal status: Prescription should be initiated and supervised by physicians experienced in the management of MS (restricted medical prescription in EU). Additional risk minimization measures: Educational Material (HCP guide and Patient card)
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None

Missing information: None

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 Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets.

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

There are no studies required for Teriflunomide Koanaa 7 mg and 14 mg film-coated tablets.