Summary of risk management plan for PIFELTRO (doravirine)

This is a summary of the risk management plan (RMP) for PIFELTRO. The RMP details important risks of PIFELTRO and how more information will be obtained about PIFELTRO's risks and uncertainties (missing information).

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

This summary of the RMP for PIFELTRO should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The Medicine and What it is Used for

PIFELTRO is authorised, in combination with other antiretroviral medicinal products, for the treatment of adults, and adolescents aged 12 years and older weighing at least 35 kg infected with HIV-1 without past or present evidence of resistance to the NNRTI class. It belongs to a group of medications called non-nucleoside reverse transcriptase inhibitors (NNRTIs), a type of antiretroviral medicine and it is given only by mouth.

Further information about the evaluation of PIFELTRO benefits can be found in PIFELTRO's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: link to product's EPAR summary landing page on the EMA webpage. https://www.ema.europa.eu/medicines/human/EPAR/pifeltro

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of PIFELTRO, together with measures to minimise such risks and the proposed studies for learning more about PIFELTRO'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, 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 PIFELTRO is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of PIFELTRO 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 PIFELTRO. 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).

Table II.A.1: List of Important Risks and Missing Information

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing Information	Safety during pregnancy

II.B Summary of Important Risks

Table II.B.1: Missing Information: Safety During Pregnancy

Risk minimisation measures	Routine risk minimisation measures: ▪ Section 4.6 and Section 5.3 of the SmPC. ▪ What you need to know before you take PIFELTRO section of Package Leaflet Additional risk minimization measures: ▪ 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 PIFELTRO.

II.C.2 Other Studies in Post-authorisation Development Plan

There are no studies required for PIFELTRO.