



Swiss Summary of the Risk Management Plan (RMP)

for

Pifeltro[®] (Doravirine)

Based on EU-RMP Version 2.0 (26-Oct-2018)

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Pifeltro is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Pifeltro in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic.

MSD Merck Sharp & Dohme AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Pifeltro.

SUMMARY OF THE RISK MANAGEMENT PLAN BY PRODUCT

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.

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 used to treat HIV infection. It belongs to a group of medications called non-nucleoside reverse transcriptase inhibitors (NNRTIs), a type of antiretroviral medicine. You should not take PIFELTRO if your doctor has told you that the virus causing your infection is resistant to the NNRTI class. It contains doravirine as the active substance 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 | <ul style="list-style-type: none"> • Safety during pregnancy • Safety during lactation • Safety in elderly patients • Long-term safety |

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 |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|

Table II.B.2: Missing Information: Safety During Lactation

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|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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, |
|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|

Table II.B.3: Missing Information: Safety in Elderly Population

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|----------------------------|---------------------------------------------------------------------------------|
| Risk minimisation measures | Routine risk minimisation measures Sections 4.2 and Section 5.2 of the SmPC. |
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Table II.B.4: Missing Information: Long-term Safety

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| Risk minimisation measures | Routine risk minimisation measures: Section 4.8 of the SmPC. |
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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.