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Swiss Summary of the Risk Management Plan (RMP) for Kyprolis® (carfilzomib)

EU RMP: Version 13.1, March 2026

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 Kyprolis® 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 Kyprolis® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. AMGEN Switzerland AG is fully responsible for the accuracy and correctness of the content of the published RMP summary of Kyprolis®.

The medicine and what it is used for

Kyprolis is used to treat adult patients with multiple myeloma who have had a least one previous treatment for this disease, in combination with daratumumab and dexamethasone, with lenalidomide and dexamethasone, or only with dexamethasone (see SmPC for the full indication). It contains carfilzomib as the active substance and it is given by intravenous route of administration.

Further information about the evaluation of Kyprolis's benefits can be found in Kyprolis's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage: <https://www.ema.europa.eu/en/medicines/human/EPAR/Kyprolis>.

Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Kyprolis, together with measures to minimize such risks and the proposed studies for learning more about Kyprolis's risks, are outlined below.

Measures to minimize 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 authorized 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 public (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse events is collected continuously and regularly analyzed including Periodic Safety Update Report (PSUR) assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

List of Important Risks and Missing Information

Important risks of Kyprolis are risks that need special risk management activities to further investigate or minimize 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 Kyprolis.

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 (eg, on the long-term use of the medicine).

Summary of safety concerns

List of important risks and missing information

Important identified risks	None
Important potential risks	Progressive multifocal leukoencephalopathy
Missing information	None

Summary of Important Risks

Important potential risk: Progressive Multifocal Leukoencephalopathy	
Evidence for linking the risk to the medicine	A small number of cases have been reported in the clinical trial and postmarket setting. A definitive diagnosis based on objective criteria (Mentzer et al, J Neurol Neurosurg Psychiatry, 2012;83:927-933) could not be established in most cases. Although a casual association with carfilzomib has not been established, there is basis for suspicion of an association considering that progressive multifocal leukoencephalopathy is typically associated with immunosuppression and has been observed with bortezomib (Velcade® Summary of Product Characteristics, 2019). Considering the small number of case reports, the strength of the evidence is moderate.
Risk factors and risk groups	Immunosuppression appears to be a risk factor for progressive multifocal leukoencephalopathy. Human immunodeficiency virus infection is the largest risk factor for progressive multifocal leukoencephalopathy. Another significant risk factor is hematological malignancy, due to the immune-suppressing treatments (Anderson et al, 2019; Koralnik, 2019; National Institute of Neurological Disorders and Stroke, 2019; Ruiz-Heredia et al, 2019; Snopkova et al, 2019; Sawicki et al, 2018; Bohra et al, 2017; Bharat et al, 2012). Beyond immunosuppression, no other risk factors are known.
Risk minimization measures	Routine risk minimization measures: - SmPC Section 4.4 where advice is given to monitor patients for any new or worsening signs and symptoms of progressive multifocal leukoencephalopathy, suspend administration until progressive multifocal leukoencephalopathy has been excluded by a specialist, and discontinue carfilzomib if a progressive multifocal leukoencephalopathy diagnosis is confirmed - PL Section 2 Additional risk minimization measures: - None

Post-authorization development plan

Studies which are a condition of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Kyprolis.

Other studies in Postauthorization Development Plan

There are no studies required for Kyprolis.