VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Not applicable

VI.2.2 Summary of treatment benefits

Sendolor is indicated for the treatment of severe acute pain, cancer pain and breakthrough cancer pain.

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Summary of safety concerns
Important identified risks - Respiratory depression - Physical dependence and withdrawal **Important potential risks** - Drug abuse - Accidental overdose - Use in patients with impaired renal function - Use in patients with hepatic impairment **Missing information** - Use in pregnancy and breastfeeding

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising those. An abbreviated version of this in lay language is provided in the form of the patient information leaflet (PIL). The measures in these documents are known as routine risk minimisation measures.

All labelling is comprehensively set up. The legal status of the product is mentioned. And the pack sizes are clearly distinguishable.

The Summary of Product Characteristics and the Patient Information Leaflet for Sendolor are publicly available.

Sendolor is subject to medical prescription.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

There is no post authorisation development plan in place for Sendolor.

VI.2.7 Summary of changes to the Risk Management Plan over time

Version	**Date**	**Safety Concerns**	**Comment**
Version 1.0	22-01-2016	Identified Risks: none Potential Risks: 1 Missing information: None	First version of the RMP submitted within the registration procedure.
Version 2.0	08-08-2016	Identified Risks: 2 Important potential risks: 4 Missing information: 1	Second version of the RMP submitted within the day 106 response of DCP NL/H/3729/001-003/DC.
Version 3.0	28-2-2017	Identified Risks: 2 Important potential risks: 4 Missing information: 1	Third version of the RMP submitted within the day 160 response of DCP NL/H/3729/001-003/DC.