VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Relief of mild nervous tension and sleep disorders.

NA. The medicinal product is considered suitable for self medication for mild and transient sleep disorders.

VI.2.2 Summary of treatment benefits

Herbal medicinal product for the relief of mild nervous tension and sleep disorders.

The sedative effects of preparations of valerian root, which have long been recognised empirically, have been confirmed in controlled clinical studies. Orally administered dry extracts of valerian root prepared with ethanol/water (ethanol maximum 70 % (V/V)) in the recommended dosage have been shown to improve sleep latency and sleep quality. These effects cannot be attributed with certainty to any known constituents.

VI.2.3 Unknowns relating to treatment benefits

The safety and efficacy of valerian root extract during pregnancy and breast-feeding, or for children under 12 years of age, have not been established.

VI.2.4 Summary of safety concerns

Missing information

Risk	**What is known**
Use in children under 12 years of age	The safety and efficacy of Sefitude has not been established for children under 12 years of age. Use in children under 12 years of age is therefore not recommended.
Use during pregnancy and breast-feeding	The safety and efficacy of Sefitude has not been established during pregnancy or lactation. Use during pregnancy and breast-feeding is therefore not recommended.

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 them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Sefitude can be found in the national competent authorities websites.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post-authorisation efficacy studies are planned.

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

Major changes to the Risk Management Plan over time

Version	**Date**	**Safety Concerns**	**Comment**
1.0	2016-05-29	Missing information: Use in children under 12 years of age Use during pregnancy and breast-feeding.	-
1.1	2016-09-05	Added: Potential: Concomitant use of other sedatives Missing information: Use in patients with impaired hepatic function Use in patients with impaired renal function	Added in response to RMS comments on Day 70 of procedure FI/H/0921/01/DC
1.2	2016-12-22	Section VI.2.2 updated in line with revised product information. Product name updated.	Updated in response to CMS comments from SE on Day 100 of FI/H/0921/01/DC and change in proposed proprietary name during the same procedure.
1.3	2017-01-03	Reversed changes made in version 1.1	In line with updated product information as harmonised with the EU herbal monograph on Valeriana officinalis, radix.