VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology (Maximum 150 words per indication)

Infiltration anaesthesia and nerve block anaesthesia

There are no European specific epidemiology data about infiltration anaesthesia and peripheral nerve blocks. In 2010, the number of anaesthesia procedure performed in France was 11 323 630, including both adult and paediatric patients. 8.2% anaesthesia procedures were performed in children under 18 years old . But the incidence and prevalence of infiltration and nerve blocks is not known, probably minor.

VI.2.2 Summary of treatment benefits

Lidocaine was first synthesised in 1943 and was used for many decades as a local anaesthetic agent. Lidocaine is currently widely used in Europe for local and regional anaesthesia. Several clinical studies confirmed lidocaine´s efficacy in this indication.

VI.2.3 Unknowns relating to treatment benefits (1 short paragraph per indication of 50 words maximum)

No extended information is available regarding the use of lidocaine as a local anaesthetics in children.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Central nervous or cardiovascular reactions following overdose/medication error	Administration of lidocaïne at a dose higher than the recommendations, or inadvertant intravascular injection may lead to potentially serious reactions affecting the cardiovascular system or the central nervous system	The administration will be performed by a healthcare professional with appropriate training and relevant experience.

Important potential risks

None

Missing information

Risk	What is known
Use in patients under 2 years of age	No extended information is available regarding the use of lidocaine as a local anaesthetics in children under 2 years of age.

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.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

None.

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

Major changes to the Risk Management Plan over time: not applicable.