VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Ketamine is indicated for starting or maintaining anaesthesia in various procedures either alone or with the assistance of other anaesthetic agens. It can be used for whole anaesthesia or for local-regional procedures. It is a well know medication that has been on the market since 1970 and its safety profile is well known. It presents with a few side effects that are easily counteracted by trained health professionals

VI.2.2 Summary of treatment benefits

Ketamine is used for preparing, inducing and maintaining anesthesia during surgical procedures. It has an important place in the practice of anesthesiology whit its unique abilities during induction of anesthesia. Ketamine remains the mainstay of anesthetic practice in patients with breathing disorders or heart related system disorders (eg reactive airway disease, hypovolemia or cardiomyopathy). It can also be considered the agent of choice in children or burn victims[1].

Ketamine is frequently used in severely injured people. A 2011 clinical practice guideline supports the use of ketamine as a dissociative sedative in emergency medicine[2]. It is the drug of choice for patients in traumatic shock who are at risk of low blood pressure (hypotension). Low blood pressure is harmful in people with severe head injury and ketamine is least likely to cause hypotension, often even able to prevent it[3].

The effect of ketamine on the respiratory and cardio vascular systems is different from that of other anesthetics. Respiratory (breathing) function is unchanged with the administration of ketamine, which makes it a valuable anaesthetic. When used at anesthetic doses, it will usually help rather than depress the circulatory system. Ketamine is considered relatively safe because protective airway (breathing) reflexes are preserved[4].

VI.2.3 Unknowns relating to treatment benefits

There is not sufficient information for the safe use of ketamine in pregnant or breastfeeding patients. Therefore, the use in these patients is not recommended.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Elevation of blood pressure	Ketamine is known to cause an increase in blood pressure with the start of an anaesthetic procedure. This increase returns to normal approximately 15minutes after the first injection. Depending on the condition of the patient, this elevation of the blood pressure may be considered an adverse reaction or a beneficial effect of ketamine.	Elevation of blood pressure can be avoided by carefully controlling the dosage of the ketamine treatment and by early recognition.
Liver impairment	Patients suffering from conditions in the liver that weaken the livers ability to metabolise ketamine are at risk of exposure to higher plasma levels of ketamine and to prolonged anaesthesia.	Patients need to inform their medical physicians of any know condition related to reduced liver function. Furthermore, medical practitioners need to take into account the patient's ability to metabolize ketamine and adjust the dose accordingly.

Important potential risks

None

Important missing information

Risk	What is known
Use in pregnancy	There is limited data on the use of ketamine during pregnancy

Risk	What is known
	in humans. There is limited data in use of ketamine during caesarian section labour or via vaginal delivery. It is not recommended to use keatamine during pregnancy. Ketamine can pass through the placenta to the foetus
Use in breastfeeding	Ketamine is passed in the breast milk, but the risk for the infant seems unlikely with normal therapeutic doses. There is limited data in use of ketamine during breastfeeding so its use cannot be recommended.

VI.2.5 Summary of additional risk minimisation measures by safety concern

Routine pharmacovigilance activities are applied.

VI.2.6 Planned post authorisation development plan (if applicable)

Not applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not applicable.