VI.2 ELEMENTS FOR A PUBLIC SUMMARY

VI.2.1 OVERVIEW OF DISEASE EPIDEMIOLOGY

Paracetamol Kabi is indicated for short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever.

Paracetamol Kabi is administration by an intravenous route. The treatment is clinically justified by an urgent need to treat pain or fever and/or when other routes of administration are not possible.

VI.2.2 SUMMARY OF TREATMENT BENEFITS

Paracetamol Kabi is indicated for the short-term treatment of moderate pain, especially following surgery and for the short-term treatment of fever, when IV administration is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible.

Intravenous paracetamol offers a more rapid time to reach a maximum level in the blood compared to oral administration. Intravenous paracetamol also avoids first-pass hepatic metabolism, which results in approximately 25% of drug removal after oral administration.

VI.2.3 UNKNOWNS RELATING TO TREATMENT BENEFITS

Paracetamol is a well-established product. There are no significant unknowns regarding the benefits of the product.

VI.2.4 SUMMARY OF SAFETY CONCERNS

Table 7 Summary of Safety Concerns

Safety Concern	What is known	Preventability
Important Identified Risks		
Use in patients with hepatobiliary disorders	The liver helps break down and remove paracetamol. Too much paracetamol overloads the liver's ability to process the drug safely. In cases of	Reduction of dosage.

Safety Concern	What is known	Preventability
	chronic alcoholism, in patients with chronic malnutrition and in patients receiving enzyme inducers more of the toxic chemical is produced than the body can easily eliminate, resulting in serious damage to the liver. The signs of liver disease include abnormally yellow skin and eyes, dark urine, light-colored stools, nausea, vomiting and loss of appetite. Liver damage, ranging from abnormalities in liver function blood tests, to acute liver failure, and even death.	
Use in patients with abnormal liver function (cases of chronic alcoholism, in patients with chronic malnutrition and in patients receiving enzyme inducers)	The liver helps break down and remove paracetamol. Too much paracetamol overloads the liver's ability to process the drug safely. In cases of chronic alcoholism, in patients with chronic malnutrition and in patients receiving enzyme inducers more of the toxic chemical is produced than the body can easily eliminate, resulting in serious damage to the liver. The signs of liver disease include abnormally yellow skin and eyes, dark urine, light-colored stools, nausea, vomiting and loss of appetite. Liver damage, ranging from abnormalities in liver function blood tests, to acute liver failure, and even death.	Reduction of dosage.

Safety Concern	What is known	Preventability
Drug interaction with anticoagulants	Taking blood thinner and paracetamol together may raise the risk of bleeding. Signs are bleeding from the gums, nosebleeds, unusual bruising, or dark stool.	Increased monitoring of the bleeding values should be conducted
Drug interaction with enzyme inducers	The liver helps break down and remove paracetamol. Too much paracetamol overloads the liver's ability to process the drug safely. In case of receiving enzyme inducers more of the toxic chemical is produced than the body can easily eliminate, resulting in serious damage to the liver. The signs of liver disease include abnormally yellow skin and eyes, dark urine, light-colored stools, nausea, vomiting and loss of appetite. Liver damage, ranging from abnormalities in liver function blood tests, to acute liver failure, and even death.	Reduction of dosage.
Risk of non-intentional overdose (due to confusion between mL and mg in neonates, and overdose in underweight adult patients)	Confusion between mL and mg in neonates, and overdose in underweight adult patients lead to liver damage	Educational materials for healthcare professionals, such as a poster and a dosing guide strip (including increments from 1 to 10 kg and correspondences between mg and mL) was developed. This is to ensure that the revised dosing table in the SmPC and Package leaflet is well known by healthcare professionals and easily accessible
Important Potential Risks – not applicable		

Missing Information		
Use in neonates and premature neonates		Checking of the body weight
Use in pregnant and lactating women		The recommended administration and duration must be strictly observed

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.

VI.2.6 PLANNED POST-AUTHORISATION DEVELOPMENT PLAN

A post-authorisation development plan is not existing.

VI.2.7 SUMMARY OF CHANGES TO THE RISK MANAGEMENT PLAN OVER TIME

There were no major changes to the Risk Management Plan over time.