VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Paracetamol is a mild analgesic and antipyretic. It is very widely used throughout the world for the short-term treatment of mild to moderate pain including toothache, headache (including migraine and tension headaches), musculoskeletal disorders, menstrual pain, neuralgia, sore throat, and for the relief of mild to moderate symptoms of common colds and flu. Paracetamol is also indicated for the treatment of osteoarthritis.

Currently there are numerous paracetamol-containing products authorised for sale in Europe and beyond. Many of these products are multi-constituent products. Single-constituent paracetamol-containing products are available for general sale in virtually all countries.

VI.2.2 Summary of treatment benefits

The use of paracetamol continues to have a very significant role to play in the treatment of mild to moderate pain, fever and related symptoms. It is effective and safe when properly used, and comparatively inexpensive.

VI.2.3 Unknowns relating to treatment benefits

Paracetamol is widely used across almost all countries in the world and all safety features of all formulations of paracetamol are well known. And all these risk are identified and addressed in SmPC and PIL.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Use in patients with hepatic and renal insufficiency	Paracetamol is contraindicated in patients with severe liver insufficiency. Paracetamol is metabolised in the liver and excreted via the kidneys	Benefits and risks of paracetamol use must be weighed carefully in these patients. Patients with severe liver damage must not take paracetamol.
Hepatotoxicity	Higher than recommended doses of Paracetamol can cause liver damage	Paracetamol should only be used at the recommended doses or as prescribed.
Medication-overuse headache	Long-term use of paracetamol may cause headaches to become worse and more frequent	Prolonged or frequent use of paracetamol should be discouraged
Drug interaction with anticoagulants	Paracetamol may cause bleeding disorders if used together with anti-coagulant drugs	Caution is required with prolonged use of paracetamol while taking anticoagulant drugs
Drug interaction with enzyme inducers	Enzyme inducing drugs can reduce plasma concentrations of paracetamol and reduce its effectiveness.	Paracetamol should not be used along with enzyme inducer drugs
Analgesic nephropathy	Prolonged use of paracetamol may result in lasting renal lesions with the risk of renal failure	Prolonged or frequent use of paracetamol should be discouraged
Use in patients with impaired nutritional status	Higher risk of toxic hepatic reactions in these patients	Prolonged use of paracetamol should be discouraged in these patients

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Overdose	Paracetamol, film-coated tablets, 500 mg, is OTC in most countries, leading to potential concurrent administration of multiple medicinal products containing paracetamol

Important missing information

Risk	What is known
None	None

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

The Summary of Product Characteristics (SmPC) of this product 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). All these risk minimization measures are given in SmPC and PL of this product.

This medicine has no additional risk minimization measures.

VI.2.6 Planned post authorisation development plan

Not Applicable

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

Ver.	Date	Summary of changes	Responsible
01	17 December 2015	Initial version	Nicolaj Donskov Nielsen
02	06 May 2015	Adaption in accordance with comments from Danish authorities	Nicolaj Donskov Nielsen
03	25 September 2015	Administrative changes for Mutual Recognition Procedure.	Nicolaj Donskov Nielsen