## VI.2 Elements for a Public Summary

### *VI.2.1 Overview of disease epidemiology*

Paracetamol/ caffeine tablets are indicated for the relief of pain and fever.

**Pain**
Paracetamol, a component of Paracetamol/caffeine, belongs to a group of medicines called analgesics (painkillers) and is used to relieve mild to moderate pain and reduce fever associated with many common pain complaints such as rheumatic and muscle pain, backache, toothache and headache. It is estimated that 20% of adults suffer from pain globally. Pain affects quality of life and restricts everyday activities even if it is short term.

**Common cold**
Common colds are most frequent from September to April in temperate climates, such as Europe. Adults and teenagers usually have 2-4 colds per year. In adults, no difference in rates of infection between men and women is apparent. Risk factors for catching a cold include if you are very young or very old or if you live under crowded conditions. Most patients will recover from a cold without any treatment, however, treatment of the symptoms with nasal decongestants or pain killers such as paracetamol is common.

**Flu (influenza)**
It is estimated that every year, worldwide, flu results in about 3-5 million cases of severe illness and about 250,000 to 500,000 deaths. Deaths are more likely in very old patients. Most patients with flu generally benefit from bed rest and recover in three days; however, a feeling of illness or weakness may last for weeks.

### *VI.2.2 Summary of treatment benefits*
Based on the available data from clinical studies and clinical experience of several years, paracetamol/caffeine represents an effective drug in the treatment of the above mentioned indications.

### *VI.2.3 Unknowns relating to treatment benefits*

Based on the currently available data, no gaps in knowledge about efficacy in the target population were identified, that would warrant post-authorisation efficacy studies. Furthermore, there is no evidence to suggest that treatment results would be different in any subgroup of the target population, for any of the indications, taking into account factors such as age, sex, or organ impairment. However, as stated in the proposed SmPC, the safety of paracetamol and caffeine in children under the age of 12 years has not been established yet.

### *VI.2.4 Summary of safety concerns*

**Important identified risks**

| Risk | What is known | Preventability |
|---|---|---|
| **Interaction with anticoagulants** | The effect of "blood thinning" medicine (anticoagulants) may be enhanced by long-term use of paracetamol. Occasional use together has no significant effect. | Paracetamol/caffeine is not intended for long term use and therefore the interaction should not pose a risk. If the product is to be used for a longer period, the effect on blood thinning agents will have to be monitored by the doctor. |
| **Interaction with enzyme inducers** | Use of enzyme inducers may increase the adverse effect of paracetamol on the liver. | Caution should be taken when paracetamol/caffeine is used together with enzyme inducers. |
| **Liver damage /Abnormal liver function (Hepatotoxicity/ abnormal liver function (including use in patients with pre-existing liver disease, chronic alcoholism, malnutrition, dehydration, underweight adults)** | There is a risk of liver damage/abnormal liver function associated with this medicine. Patients with liver damage and/or abnormal liver function may experience additional side effects. | Patients with liver damage and/or abnormal liver function should seek medical advice prior to taking this medication. |
| **Overdose (non-intentional and intentional) (Taking too much of this medicine)** | There is a risk of intoxication due to paracetamol overdose, especially for the elderly, small children, patients with liver disease, in cases of chronic alcoholism and patients with chronic malnutrition. An overdose of paracetamol may be fatal. | The maximum daily dose of paracetamol must not be exceeded. If an overdose is suspected, the appropriate emergency treatment should be initiated. |
| **Use in children under 12 years of age** | The safety and effectiveness of this medication has not been studied in children under 12 years of age. | **Use in children under 12 years of age** |

**Important potential risks**

| Risk | What is known (Including reason why it is considered a potential risk) |
|---|---|
| **Medication overuse headache** | After long term treatment (> 3 months) of paracetamol with use every second day or more frequently, headache may develop or become worse. Headache caused by overuse of paracetamol should not be treated by increasing the dose of paracetamol. In such cases treatment with paracetamol should be discontinued. |

### *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 ParaPlus can be found at the homepage of the National Health Authorities.

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*

Not applicable as this is the initial risk management plan.