Para-Caps 500 mg capsule, soft

1.12.2015, Version 1.2

Public Summary of the Risk Management Plan

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Para-Caps 500 mg is indicated for temporary pain and fever, like influenza, cold, headache, nerve-, muscle-, dental- and menstrual pain.

Pain is a complex biological phenomenon that can be caused by multiple diseases or conditions. Examples of different pain conditions include post-operative pain, pain due to musculoskeletal disease states and cancer-related pain. Pain can restrain in one area of the body, such as back or stomach, or it may feel all over, such as muscle ache due to flu. Pain can last for a short time or last beyond the healing of an injury and become chronic.

Fever is a temporary increase in body temperature (hypertermia) in response to a disease or illness. Fever plays a key role in body's defense against infection by activating the immune system. Fever isn't usually dangerous, but sometimes excessive hyperthermia can cause dangerous rises in body temperature.

The exact prevalence of pain and fever are difficult to assess but can be considered as very common symptoms.

VI.2.2 Summary of treatment benefits

Pain can be harmful or even restricting for the patient. Pain decreases the quality of life and can also restrict the ability to work. Thus, appropriate and effective treatment of pain is important. Temporary elevations in body temperature caused by acute illnesses are usually well-tolerated by healthy adults. Prolonged or extreme temperature elevation can be however damaging and in those cases it is important to lower the fever.

Para-Caps 500 mg soft capsule is indicated for both adults and children. The active substance is paracetamol which affects the central nervous centres regulating the body temperature, increases heat loss and lowers fever. The precise mechanism of the pain relieving properties is unknown. Paracetamol, like other painkillers (like non-steroidal anti-inflammatory drugs, NSAIDs), can cause adverse effects. Therefore the treatment should optimally be only for short-term and the used dosages should be the lowest doses that are effective. Paracetamol is known to be a safer option for the stomach in terms of adverse effects (bleeding and ulcers) as compared with NSAIDs.

VI.2.3 Unknowns relating to treatment benefits

The safe use of paracetamol for long periods, at high doses or in combination with other medicinal products during pregnancy has not been established. This kind of treatment is therefore not recommended during pregnancy.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Liver damage/ abnormal liver function (Patients with pre-existing liver disease, chronic alcoholism, malnutrition, dehydration, underweight adults)	Paracetamol may adversely affect the function of the liver, even when it is used at therapeutic doses, in short-term and in patients with no history of abnormal liver function. In case of overdose, paracetamol may cause liver damage that can be seen in 1-4 days. Paracetamol is extensively metabolised (transformed into a form that is easier for the body to eliminate) in the liver. Therefore, in patients with impaired function of the liver, the amounts of paracetamol may increase and cause adverse effects. In certain patient groups, like alcoholics, anorectics or malnourished patients the risk for adverse effects on the liver is increased.	Concomitant use of other paracetamol-containing medicines should be avoided. In patients with liver impairment, Para-Caps should not be used. These patients are advised to contact a doctor/pharmacist before they use Para-Caps. Paracetamol is not recommended for long-term use and maximal doses especially with alcoholics, anorectics or malnourished patients because these patient groups have increased risk of liver damage. In the case of an overdose, despite the lack of significant early symptoms, the patient should be referred to hospital where the liver function should be tested and substance with counteracting effect (antidote) should be given when applicable.
Overdose (non-intentional and intentional)	There is a risk of accidental or intentional overdose when paracetamol is used. Certain patient groups are at particular risk of overdose; elderly patients, young children, persons with hepatic disease, chronic alcohol abuse, chronic malnutrition and those concurrently taking medicinal products that lead to enzyme induction. In such cases, overdose can be fatal. Concomitant use with other medications containing paracetamol will increase the risk of overdose.	The patients are instructed with the right and maximum daily dose in the patient information leaflet. Patients who have liver disease can not use paracetamol. Maximum and prolonged use of paracetamol is not recommended in patients with alcoholism, anorexia or malnourishment. Other medications containing paracetamol should not be used concomitantly with Para-Caps.
Drug interaction with medications that prevent blood clots (anticoagulants)	When paracetamol is used temporarely with recommended doses, it should not affect the	In long-term use and when used in doses over 2 g daily, the patient with concomitant

Risk	What is known	Preventability
	efficacy of anticoagulants. But when it is used in high doses or prolonged time concomitantly with anticoagulants, the risk for bleeding will increase.	anticoagulant medication should contact his/her doctor.
Drug interaction with substances that are enzyme inducers	Enzyme inducers, such as phenytoin, phenobarbital and carbamazepine (antiepileptic drugs), may reduce the concentration of paracetamol in the body. The concomitant use with substances which burden the liver like alcohol, barbiturates (antiepileptic and hypnotic drugs) and zidovudine (HIV medicine), may increase the adverse effects of paracetamol on the liver.	If a patient is using medications like antiepileptics or barbiturates the patient is advised to talk to his/her doctor before taking paracetamol. Para-Caps and alcohol should not be used together.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Medication overuse headache	When paracetamol is used, it may cause on rare occations an adverse effect of headache.

Missing information

Risk	What is known
Off-label use (use > 14 days)	Long-term use of paracetamol may increase the risk of kidney damage. Prolonged use of paracetamol in alcoholics, anorectics or malnourished patients may increase the risk of adverse effects on the liver.
Use in children < 16 years	-
Medication errors	There is a risk that Para-Caps is not used as instructed. Medication errors may lead to mild to severe adverse effects of paracetamol.

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 Para-Caps 500 mg soft capsules can be found in the national authority's web page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Not applicable.

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

Not applicable.