VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Paraseu is indicated for the short-term symptomatic relief of conditions in which swelling of the mucous membranes of the upper respiratory tract, especially the nasal mucosa and sinuses, is accompanied by mild to moderate pain or fever, for example colds, flu, sinusitis and nasopharyngitis.
Paraseu is indicated in adults and children over the age of 15 years.

Adults have an average of between two and four colds a year. Children have up to 12 colds a year. Annual epidemics occur within the colder months in temperate climates and during the rainy season in the tropics. There are over 200 viruses which cause colds, and many people suffering from cold symptoms are found to be infected with several viruses at the same time. [1]
The most frequent symptoms are nasal discharge, nasal obstruction, sore throat, headache, and cough. Hoarseness, loss of taste and smell, mild burning of the eyes, and a feeling of pressure in the ears or sinuses, due to obstruction and/or mucosal swelling, may also occur.
Cough is associated with 30% of colds and tends to start on about the fourth or fifth day when nasal symptoms decrease. There may be a mild increase in body temperature. Infants and young children are more likely to develop higher temperatures. In infants there may be irritability, snuffles resulting in difficulty feeding, and diarrhoea. Diagnosis may be difficult and fever can be the main symptom during the early part of the illness. [2]
There seems to be no noticeable difference between men and women.

VI.2.2 Summary of treatment benefits

Paracetamol and pseudoephedrine are widely used in different formulation and there is sufficiently documented human experience of their individual and combined use.
Clinical study showed the treatment with Paracetamol/Pseudoephedrine combination was safe and highly effective in reducing symptoms during colds or associated with seasonal allergic rhinitis, nasal congestion, and with paranasal sinuses that may develop early in the course of a cold. Paracetamol is widely used as the major ingredient in combination medications for the common cold and randomised controlled trials have found that paracetamol is an effective and safe treatment for the common cold. Pseudoephedrine is widely used for the treatment of nasal congestion associated with common cold and its efficacy was confirmed by clinical trials.

VI.2.3 Unknowns relating to treatment benefits

None.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Overdose	Paracetamol Acute poisoning is seen at doses above 6 g for adults and over 125 mg/kg for children. Prolonged overdose occurs at doses above 4 grams / day for adults and over 90 mg/kg/day for children. For children weighing more than 50 kg, overdose occurs at the same doses as for adults. Symptoms Very common symptoms of paracetamol overdose within the first 24 hours are bleeding, nausea, vomiting, anorexia and abdominal pain. Liver damage may occur 12-48 hours after ingestion. Disturbances in glucose metabolism and metabolic acidosis may occur. In severe poisoning, liver failure may result in abnormal brain function (encephalopathy), coma and death. Acute kidney failure may occur, even without the presence of severe liver injury. Cardiac arrhythmias and infection of pancreas (pancreatitis) have been reported. Pseudoephedrine Symptoms of overdose are typically seen after 4-5 times therapeutic doses (maximum therapeutic dose is 240 mg/day). Symptoms Like other sympathomimetic drugs, symptoms and signs of overdose may include Irritability, restlessness, tremor, cramps, palpitations, hypertension and difficulty in urination.	As the medicine contains paracetamol other medicines containing paracetamol should not be taken. The indicated dose should not be exceeded. Treatment: The doctor should be contacted immediately in case of overdose, due to the risk of irreversible liver damage.
Taking Paraseu together with (concomitant) other drugs	Taking Paraseu together with other drugs with effects like Paraseu are a known contra-indication and patients with this risk should therefore not use Paraseu as listed in the product information might have unwanted effects. The concerned drugs are: Monoamine oxidase inhibitors (MAOIs), Other sympathomimetics against nasal congestion, furazolidone, beta blockers, other sympathomimetics (eg anorexia or amphetamine-like psychostimulants), tricyclic antidepressants, antocolinergics, furazolidine, oxytocine, cardiac glycosides, ergotalcaloids, halogenated anesthetic agents, barbiturates, alcohol, enzyme inducing agents, metoclopramide, domperidone, colestyramine, warfarin and other coumarines.	The risk can be reduced by not allowing the product to be used in patients who take relevant other medicines as mentioned in the product information. Attention must be paid not to simultaneously be given oral preparations containing drugs with effect like Paraseu via several different routes, ie orally and topically (preparations administered via the nose, ears or eyes).

Risk	What is known	Preventability
Difficulty in urinating (urinary retention)	Urinary retention has been reported as a possible adverse reaction in men receiving pseudoephedrine. Enlarged prostate may have been an important predisposing factor.	The risk can be reduced by paying attention if the product is used in patients who have difficulty in urinating and in men with enlarged prostate glands.
Increased blood pressure (Hypertension)	Paraseu shall not be used if the patient suffer from high blood pressure (hypertension) – Hypertension is a known contraindication. Use of the following drugs together with Paraseu may increase the risk: Monoamine oxidase inhibitors (MAOIs), other sympathomimetics (eg anorectics or amphetamine-like psychostimulants), tricyclic antidepressants (TCAs). Increased blood pressure (hypertension) is a possible undesirable effect of unknown frequency with Paraseu treatment.	The risk can be reduced by not using the product in patients who suffer from increased blood pressure (hypertension). The risk can be reduced by not using medicine together with Paraseu which may increase the risk.
Increased heart rate (Tachycardia)	Tachycardia is a possible undesirable effect with Paraseu treatment.	There is no specific measure to prevent the occurrence.
Irregular heartbeat (Arrhythmia)	Arrhythmia is a possible undesirable effect with Paraseu treatment. Medicine called cardiac glycosides may increase the risk of irregular heartbeat. Medicine called halogenated anesthetics such as chloroform, cyclopropane, halothane, enflurane or isoflurane can provoke or exacerbate irregular heartbeat.	There is no specific measure to prevent the occurrence. The risk can be reduced by not using medicine together with Paraseu which may increase the risk.

Missing information

Risk	What is known
Use in pregnancy	There are no relevant data for the use of the combination of paracetamol and pseudoephedrine in pregnant women and lactating women. Pregnancy The medicine should not be used during pregnancy.
Use in children under 15 years of age	This medicine should not be used in children under 15 years of age.
Effect on Fertility	There are no data on the effects of Paraseu on human fertility.

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 Paraseu can be found at the homepage of the National Health Authority.

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.