VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Parkinson's disease results from progressive damage to the nerve cells in the area of the brain responsible for controlling muscle tone and movement. The damaged cells are those needed to produce a neurotransmitter (chemical messenger in the brain that transmits information from one nerve cell to another) called dopamine. Patients with Parkinson's disease have low levels of dopamine. Parkinson's disease occurs primarily, but not exclusively, in the elderly. The symptoms of Parkinson's disease are bradykinesia (slowness and poverty of movement), muscular rigidity, resting tremor and an impairment of postural balance. The cause of Parkinson's disease is not known in the vast majority of the cases.

Oral treatment with a dopamine precursor called levodopa is effective in the early stages of the disease. The brain still has the ability to store dopamine precursor and transform it into dopamine. As the disease progresses, the brain loses this ability to store or use its reserves of dopamine precursor. Patients that reach the advanced stages of Parkinson's disease have several motor and non-motor complications, which dramatically impair their quality of life.

VI.2.2 Summary of treatment benefits

LECIGON is a medicine that contains three active substances: levodopa, carbidopa and entacapone. It is used to treat adults with Parkinson's disease when oral combinations of Parkinson medicinal products have not given satisfactory results. The treatment with LECIGON aims at creating a balance between the benefit and side effects of the treatments available. LECIGON was developed to combine the advantages of intestinal administration with those of the oral fixed combination of levodopa, carbidopa and entacapone.

VI.2.3 Unknowns relating to treatment benefits

One clinical study has been performed with the product. This was a short-term study in a small number of patients. This study indicated that a 20-35% reduction of the levodopa dose when given as LECIGON (with entacapone) compared to the levodopa dose given with levodopa and carbidopa as an intestinal gel (without entacapone) would result in the same effect.

Long-term efficacy and safety of the levodopa, carbidopa and entacapone oral triple combination medication and the levodopa and carbidopa combination as an intestinal gel are well-known and these products have been on the market for more than 10 years. The main difference of LECIGON compared with current available treatments is the route of administration of the levodopa, carbidopa and entacapone.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Heart or artery disease events (e.g. chest pain) and heart attack.	When treated with LECIGON, there is a risk for heart or artery disease events (e.g. chest pain) or heart attack. LECIGON therapy should be administered with caution to patients with heart or artery disease events (e.g. chest pain), severe heart and blood vessel disease or lung disease.	Talk to your doctor before taking LECIGON if you have or have ever had a heart attack or any other diseases of the heart including heart or artery disease events (e.g. chest pain) or irregular heart rate or rhythm. Some asthma and allergy medications may increase heart and vessel side effects of LECIGON. Talk to your doctor if you use this type of medication. At long term treatment with LECIGON, it is recommended to regularly check your heart function.

Important potential risks

Not applicable.

Missing information

Risk	What is known
Use in pregnancy and breast-feeding	Not studied with LECIGON. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. LECIGON is not recommended during pregnancy and in females of childbearing potential not using contraception unless the benefits for the mother outweigh the possible risks to the foetus. You should not breast-feed during treatment with LECIGON.
Clinical relevance of hydrazine content	LECIGON contains hydrazine, a breakdown product of carbidopa which may damage your genetic material which could lead to cancer. The expected average daily dose of LECIGON is 50 mL (corresponding to 1.75 mg hydrazine / day) and the maximum recommended daily dose of Lecigon 100 mL (equivalent to a maximum of 3.5 mg hydrazine / day). The clinical significance of this exposure to hydrazine is not known.

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. The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Not applicable.

List of studies in post authorisation development plan

Not applicable.

Studies which are a condition of the marketing authorisation

Not applicable.

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

Not applicable, this is the first version of the RMP.