VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

This medicinal product is only indicated for diagnostic testing of lung function.

VI.2.2 Summary of treatment benefits

As the lung test gas is a diagnostic preparation, the product is not used to treat a disease and no pharmacological effect is wanted.

The lung test gas is odourless and tasteless and should only be administered through inhalation in conjunction with diagnostic testing of lung function.

The lung function is determined by measuring the diffusion capacity and estimation of lung volume and blood flow in the lungs. The diffusion capacity measures how well oxygen passes from the lung to the blood. In lung disease it is more difficult for oxygen to reach the blood, and thus the oxygenation of the blood is worsened.

Measurements must only be carried out by medical personnel, competent and trained to perform lung function tests in accordance with the instructions for the measuring equipment.

VI.2.3 Unknowns relating to treatment benefits

The lung test gas is a well-established medicinal product used for lung testing. Thus, no pharmacological effect is wanted and there is no known side effect for the lung test gas.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
None	Not applicable	Not applicable

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Risk of increasing carboxyhaemoglobin level in the blood	Oxygen is bound to haemoglobin when it is transported in the blood. Also carbon dioxide binds to haemoglobin (carboxyhaemoglobin) which then prevents the binding and transport of oxygen in the body. Subsequently this leads to an increased level of carboxyhaemoglobin and a decreased level of oxygen available in the blood, which could cause shortness of breath. If the gas is inhaled continuously or repeatedly at short intervals during a longer period, the carboxyhaemoglobin level may rise. On suspected overdose, the patient must immediately be given oxygen via mask and a blood test taken to determine the carboxyhaemoglobin level must be taken. If signs of hypoxia, vascular spasm, impaired consciousness or other diffuse symptoms should occur, the patient must undergo acute medical assessment without delay

Missing information

Risk	What is known
None	The product is well-characterised and has been on the market and used for many years, therefore there is no missing information.

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 (PL) for this medicine can be found at the Heads of Medicines Agencies (HMA) homepage under MRI product index. The product name Lung test gas CO/C2H2/CH4 AGA, links to the latest approved versions of the SmPC and PL approved in SE/H/1153/01/R/001:

Final SPC https://www.lakemedelsverket.se/LMF/Lakemedelsinformation/?nplid=20060103000035

Final SPC https://www.lakemedelsverket.se/LMF/Lakemedelsinformation/?nplid=20060103000035

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

The product has been authorised based on the well-established use and authorised according to article 10a. In addition the product has been approved based on a bibliographical application with safety and efficacy information taken from the public domain. There is no post authorisation development plan including any clinical studies. There are no clinical studies as condition of any marketing authorisation.

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

This is the first version of the Risk Management Plan for Lung Test Gas $CO/C_2H_2/CH_4$ and therefore this section is not applicable.