

SUMMARY OF RISK MANAGEMENT PLAN FOR MEDICINSK OXYGEN

“AIR LIQUIDE” 100%

This is a summary of the risk management plan (RMP) for MEDICINSK OXYGEN “Air Liquide”100%. The RMP details important risks of MEDICINSK OXYGEN “Air Liquide” 100% how these risks can be minimised, and how more information will be obtained about MEDICINSK OXYGEN “Air Liquide” 100%'s risks and uncertainties (missing information).

MEDICINSK OXYGEN “Air Liquide” 100%'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how MEDICINSK OXYGEN “Air Liquide” 100% should be used.

Important new concerns or changes to the current ones will be included in updates of MEDICINSK OXYGEN “Air Liquide”'s RMP.

Module 1.8.2

Risk-management system

I. THE MEDICINE AND WHAT IT IS USED FOR

MEDICINSK OXYGEN “Air Liquide” 100% is authorised for :

Oxygen therapy

- For treatment or prevention of acute and chronic hypoxia irrespective of cause.
- As part of the fresh gas flow in anaesthesia or intensive care.
- As the propellant in nebuliser treatment.
- For treatment of an acute attack of cluster headache

Hyperbaric oxygen therapy

For treatment of decompression sickness, air/gas emboli from other causes and carbon monoxide poisoning. Treatment of patients who have been exposed to carbon monoxide, is especially indicated in pregnant patients or patients who are or have been unconscious, or who have displayed neurological symptoms and/or cardiovascular effects or severe acidosis, irrespective of the measured COHb value.

As adjunct treatment in severe osteoradionecrosis, clostridium myonecrosis (gas gangrene).

It contains OXYGEN as the active substance and it is given by inhalation route.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISK

Important risks of MEDICINSK OXYGEN “Air Liquide” 100% together with measures to minimise such risks and the proposed studies for learning more about MEDICINSK OXYGEN “Air Liquide” 100%'s risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A LIST OF IMPORTANT RISKS AND MISSING INFORMATION

Important risks of MEDICINSK OXYGEN “Air Liquide” 100% are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of MEDICINSK OXYGEN “Air Liquide” 100%. Potential

risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B SUMMARY OF IMPORTANT RISKS

Not applicable

II.C POST-AUTHORISATION DEVELOPMENT PLAN

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of MEDICINK OXYGEN "Air Liquide" 100%.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for MEDICINK OXYGEN "Air Liquide" 100%.