

Summary Public Assessment Report

Medicinsk Oxygen Air Liquide (oxygen)

SE/H/1054/01/E01

Summary Public Assessment Report

Medicinsk Oxygen Air Liquide
(oxygen)

medicinal gas, compressed; 100 %

This is a summary of the public assessment report (PAR) for Medicinsk Oxygen Air Liquide. It explains how Medicinsk Oxygen Air Liquide was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Medicinsk Oxygen Air Liquide.

For practical information about using Medicinsk Oxygen Air Liquide, patients should read the package leaflet or contact their doctor or pharmacist.

What is Medicinsk Oxygen Air Liquide and what is it used for?

Medicinsk Oxygen Air Liquide is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of Medicinsk Oxygen Air Liquide is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Medicinsk Oxygen Air Liquide is used:

- To treat or prevent acute or chronic oxygen deficiency
- As a propellant for inhalation of other medicinal products (nebuliser treatment)
- As part of the gas flow in anaesthesia, pain relief and intensive care
- In pressurised chambers to reduce the risk of damage caused by decompression sickness, gas or air bubbles in blood vessels and in treatment of severe carbon monoxide poisoning and gangrene
- For treatment of an acute attack of cluster headache

How does Medicinsk Oxygen Air Liquide work?

Medicinal Oxygen Air Liquide contains oxygen and increases the level of oxygen in the blood (increased oxygen saturation). This results in more oxygen being transported to all the tissues in the body.

How is Medicinsk Oxygen Air Liquide used?

The pharmaceutical form of Medicinsk Oxygen Air Liquide is compressed medicinal gas which is used for inhalation.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can be obtained without a prescription.

What benefits of Medicinsk Oxygen Air Liquide have been shown in studies?

As oxygen is a well-known substance, and its use in the approved indications:

- *To treat or prevent acute or chronic oxygen deficiency*
- *As a propellant for inhalation of other medicinal products (nebuliser treatment)*
- *As part of the gas flow in anaesthesia, pain relief and intensive care*
- *In pressurised chambers to reduce the risk of damage caused by decompression sickness, gas or air bubbles in blood vessels and in treatment of severe carbon monoxide poisoning and gangrene*
- *For treatment of an acute attack of cluster headache*

are well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of oxygen in the treatment of the above mentioned indications.

What are the possible side effects of Medicinsk Oxygen Air Liquide?

For the full list of all side effects reported with Medicinsk Oxygen Air Liquide, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Medicinsk Oxygen Air Liquide approved?

The use of Medicinsk Oxygen Air Liquide:

- *To treat or prevent acute or chronic oxygen deficiency*
- *As a propellant for inhalation of other medicinal products (nebuliser treatment)*
- *As part of the gas flow in anaesthesia, pain relief and intensive care*
- *In pressurised chambers to reduce the risk of damage caused by decompression sickness, gas or air bubbles in blood vessels and in treatment of severe carbon monoxide poisoning and gangrene*
- *For treatment of an acute attack of cluster headache*

is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Medicinsk Oxygen Air Liquide's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Medicinsk Oxygen Air Liquide?

A risk management plan has been developed to ensure that Medicinsk Oxygen Air Liquide is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Medicinsk Oxygen Air Liquide, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Medicinsk Oxygen Air Liquide

The marketing authorisation for Medicinsk Oxygen Air Liquide was granted on 2009-06-04 in Sweden.

The full PAR for Medicinsk Oxygen Air Liquide can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Medicinsk Oxygen Air Liquide, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2018-04-26.