SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lung test gas, CO/He Linde 0.28%, 9.3% medicinal gas, compressed

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbon monoxide (CO) 0.28% under 150 bar pressure (15°C)Helium (He) 9.3% under 150 bar pressure (15°C)
For a full list of excipient, see section 6.1

3 PHARMACEUTICAL FORM

Medicinal gas, compressed. Colourless, odourless and tasteless gas

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.
For diagnostic testing of pulmonary function (determination of the diffusion capacity/transferfactor as main parameter and the estimation of lung volume as additional parameter).
Lung test gas, CO/He Linde may only be used in patients capable of performing the test,irrespective of age.

4.2 Posology and method of administration

Posology

The medicinal gas is inhaled for a single-breath, which may be repeated at intervals for a maximum of five times per session.

Method of administration

Only for inhalation in conjunction with diagnostic testing of pulmonary function. The gas mustbe used in accordance with measuring equipment instructions. Measurements must only be carried out by medical personnel competent and trained to perform pulmonary function tests.

4.3 Contraindications

None documented.

4.4 Special warnings and precautions for use

The risk of increasing the carboxyhaemoglobin level should be considered during repeated inhalations within a brief period (minutes). If the gas is inhaled continuously or repeatedly atshort intervals over an extended period of time, the carboxyhaemoglobin level may rise and should be checked by means of a blood gas determination.
This product should be used with caution in children because of the lack of systematic toxicitydata for this mixture.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data of the use of Lung test gas CO/He Linde in pregnant women.

There are reports of use of CO containing lung test gases during pregnancy up to a [HbCO] of 5% per testing session when the dose-exposure limit is 0.3% CO inhalation for ≤3 min. For smokers (whose maternal [HbCO] is already at about 5%), then CO exposure that is ≤1 min at aconcentration of 0.3% (3000 ppm) has been proposed.

Animal studies have shown fetotoxic effects after exposure to carbon monoxide, far in excess to exposure associated with the clinical use of Lung test gas CO/He Linde.

Pulmonary diffusion capacity testing with Lung test gas CO/He Linde should be avoided during pregnancy unless strictly necessary.

Breast-feeding

Lung test gas CO/He Linde may be used during the breast-feeding period.

Fertility

The potential effect of clinical doses of Lung test gas, CO/He Linde (associated with diagnostictesting of pulmonary function) on fertility in patients, is unknown. No data are available.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None known.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important.It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Symptoms

Carbon monoxide poisoning is characterized by signs of reduced oxygen intake, which include impaired consciousness or neurobehavioral symptoms, headache, dizziness, nausea, vomiting and blurred vision; chest pain, dyspnoea, weakness or other vague symptoms.

On suspected overdose, the testing should be interrupted immediately.

Management

On suspected overdose, patients must immediately be given oxygen by mask and a blood test (blood gas) to determine the carboxyhaemoglobin level must be taken. Oxygen should be given until the carboxyhaemoglobin concentrations are less than 5% (confirmed by blood gas analyses).
If signs of severe hypoxia, vascular spasm (e.g. angina pectoris), impaired consciousness or other

diffuse neurobehavioral symptoms occur, the patient must undergo acute medical assessment without delay.

Carbon monoxide
Carbon monoxide produces tissue hypoxia by binding to Hb, displacing O2 from it, and forming COHb (carboxyhaemoglobin), which has less O2-carrying capacity of blood and impairs release of O2 from Hb in tissues. Carbon monoxide-induced hypoxia triggers compensatory cardiovascular responses that include increased cardiac output and dilation ofcardiac and cerebral vasculature.

Helium
Helium is biochemically and biologically inert, but in high ambient concentrations it causes hypoxia and asphyxia by displacement of oxygen.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic preparations.ATC code: V04CX

The product is intended for diagnostic purpose only and no biological effects should be expected. Brief exposure in combination with the concentration of carbon monoxide and helium used is unlikely to cause any biological effects irrespectively of age when used asindicated.
See also a special warning for children in Section 4.4.

5.2 Pharmacokinetic properties

Diffusion of carbon monoxide from the lung to capillary blood depends on the partial gas pressure in the alveolus. Uptake of carbon monoxide takes place only in pulmonary segments with alveolar ventilation and perfusion. The uptake is also dependent on the alveolocapillary parenchyma. The uptake is impaired by illness, inflammatory processes and/or fibrosis. In theblood, carbon monoxide binds to haemoglobin to form carboxyhaemoglobin.

The uptake of carbon monoxide is governed by the partial pressure in the lung, ventilation- perfusion conditions, and by alveolocapillary permeability. Especially in parenchymatous lungchanges, the carbon monoxide diffusion capacity decreases and uptake is diminished.

Helium is an inert noble gas that is not taken up by the body thus it will mix in the entire lung volume and the dilution will be used for estimation of the lung capacity. There is no human kinetics associated to the administration of trace concentration in conjunction with lungfunction testing, single or repeated breath techniques, lung volume estimate.

5.3 Preclinical safety data

No preclinical data of relevance to the safety assessment are available except as referencedabove in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Oxygen 20.9% (oxygen, chemical formula O_2)
Nitrogen q.s. (nitrogen, chemical formula N_2)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Storage instruction relating to the medicinal product
No specific storage instructions are required for this medicinal product with respect to temperature, except as applicable to gas containers and gas under pressure (see below).Store the cylinders in a locked area reserved for medical gases.

Storage instructions relating to gas containers and gases under pressure Must not be exposed to strong heat. If at risk of fire – move to a safe place.Handle carefully.
Must be returned with 5 bar overpressure.
Cylinders must be stored and transported with valves closed and, with the protective cap inplace.

6.5 Nature and contents of container

The shoulder of the gas cylinder carries light green markings (inert gas). The body of the gascylinder is white (medical gas).

Packages (including materials) and valves:

10 litre aluminium cylinder with shut-off or residual pressure valve containing approx. 1500 litre of gas.

20 litre aluminium cylinder with shut-off or residual pressure valve containing approx. 3000 litre of gas.

6.6 Special precautions for disposal and other handling

General

Medical gases may only be used for medicinal purposes.

Cylinders containing different types and qualities of gases should be kept segregated. Full andempty cylinders should be stored separately.
Never use oil or grease, even if the cylinder valve sticks or if the regulator is difficult to connect.
Handle valves and devices belonging to them with clean and grease-free (hand-cream,etc.) hands.
Cylinders should be stored under cover, protected against weather and wind, kept dry andclean, free from inflammable material and not subjected to strong heat.
Use only standard devices that are designed for medicinal use. Check that the cylinders are sealed before they are taken into use.

Preparation for use
Remove the seal from the valve before use.
Use only regulators designed for medicinal purposes. Check that the regulator is clean and thatthe gaskets are in good condition.
Open the cylinder valve gently and pressurize the regulator, close the valve. Depressurise theregulator. Repeat 3 times.
Check for leakage according to instructions that accompany the regulator. Do not attempt to remedy leakage from the valve or device in any way other than by changing the pack or O-ring.In the event of leakage, close the valve and uncouple the regulator. Label defective cylinders, put them aside, and

return them to the supplier.

Using the gas cylinder
Smoking and naked flames are absolutely forbidden in areas when gas therapy is given.Close down the equipment in the event of fire or if it is not being used.
Carry to safety in the event of fire.
When the cylinder is in use, it should be secured in an appropriate support. Precautions should be taken to prevent blows or falls during storage and transport.

The product must not be used at a pressure under 5 bar. This residual pressure protects thecylinder from contamination.

After use, the cylinder valve should be closed with normal force. Depressurise the regulator or connection.

7 MARKETING AUTHORISATION HOLDER

Linde Sverige AB
Rättarvägen 3
169 68 Solna
Sweden

8 MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2009-08-21/ 2014-08-21

10 DATE OF REVISION OF THE TEXT

2025-03-05