

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lung Function Medical Gas Mixture 4

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lung Function Medical Gas Mixture 4 is a medicinal gas mixture of Carbon Monoxide, Helium, Oxygen and Nitrogen. The Oxygen and Nitrogen comply with the relevant European Pharmacopoeia Specifications (1998).

The Helium complies with the British Pharmacopoeia Specification (1988).

The mixture specification is as follows:

| | |
|-----------------|--------------------|
| Carbon Monoxide | 0.30 % + / - 0.03% |
| Helium | 10.00% + / -0.50% |
| Oxygen | 21.00% + / -1.00% |
| Nitrogen | Balance |

3. PHARMACEUTICAL FORM

Inhalation Gas

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Lung Function Medical Gas Mixture 4 is used in pulmonary function tests to measure gas transfer in the lung. Carbon monoxide is more easily absorbed than helium. By differential calculation, deficiencies in gas transfer and diffusion across the alveolar membrane can be measured.

4.2 Posology and method of administration

Lung Function Medical Gas Mixture 4 is administered through the lungs by inhalation through volumetric metering and absorption analysis devices. It may be administered by mask or by means of a tent.

4.3 Contra-indications

There are no contra-indications for the use of Lung Function Medical Gas Mixture 4 in any age group.

The use and dosage of Lung Function Medical Gas Mixture 4 is determined entirely by the respiratory function test being applied.

There are no distinctions between children, adults and the elderly, but patients with cardiac or lung disorders who require therapeutic oxygen will require more oxygen than in the mixture. This is determined by the investigator.

0.28% may be a lethal concentration if continued for some 30 minutes 2000 ppm (0.20%) will cause unconsciousness due to poisoning after 30 minutes at rest or 10 minutes exertion.

4.4 Special warnings and special precautions for use

Lung Function Medical Gas Mixture 4 is used for diagnostic and research purposes.

The mixture contains carbon monoxide that is toxic, and not more than a few full breaths should be taken because of its great affinity for haemoglobin.

Care is needed when handling Lung Function Medical Gas Mixture 4 cylinders.

4.5 Interactions with other medicinal products and other forms of interaction

None applicable.

4.6 Pregnancy and lactation

Lung Function Medical Gas Mixture 4 does not adversely affect pregnancy and lactation.

4.7 Effects on ability to drive and use machines

In normal circumstances, Lung Function Medical Gas Mixture 4 does not effect ability to drive or to operate machinery.

4.8 Undesirable effects

None Applicable

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 Yellow Card System www.mhra.gov.uk/yellowcard

4.9 Overdose

None applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The characteristics of Carbon Monoxide are:

- odourless, colourless gas
- Molecular weight 28
- Boiling point -192°C (at 1 bar (g))
- Density 1.165 kg/in³ (at 15°C)

The characteristics of Helium are:

- odourless, colourless gas
- Molecular weight 4
- Boiling point -269°C (at 1 bar (g))
- Density 0.169 kg/m³ (at 15°C)

Helium has no physiological activity and will not support life.

The characteristics of Oxygen are:

- odourless, colourless gas
- Molecular weight 32
- Boiling point -183.1⁰C (at 1 bar (g))
- Density 1.355 kg/m³ (at 15⁰C)

Oxygen is present in the atmosphere at 21% and is an absolute necessity for life.

The characteristics of Nitrogen are:

- odourless, colourless gas
- Molecular weight 28
- Boiling point -196°C (at 1 bar (g))
- Density 1.185 kg/m³ (at 15°C)

Nitrogen is a non-toxic inert gas. It has no physiological activity and will not support life.

5.2 Pharmacokinetic properties

None applicable.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Lung Function Medical Gas Mixture 4 is chemically inactive and will not react with other compounds at normal temperatures.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Lung Function Medical Gas Mixture 4 cylinders should be stored as follows:

- Cylinders should be stored under cover, preferably inside, kept dry and clean and not subjected to extremes of heat or cold away from stocks of material.
- Cylinders should not be stored near stocks of combustible materials or near sources of heat.
- Medical cylinders should be stored separately from industrial and other non-medical cylinders.
- Full and empty cylinders should be stored separately.
- Full cylinders should be used in strict rotation.
- Segregate medical cylinders containing different gases within the store.
- Warning notices prohibiting smoking and naked lights must be posted clearly.
- Emergency services should be advised of the location of the cylinder store.

6.5 Nature and contents of container

Lung Function Medical Gas Mixture 4 Cylinder and Valve Details

All cylinders used for the storage of Lung Function Medical Gas Mixture 4 are manufactured from aluminium with a designed working pressure of at least 150 bar (g).

A summary of Lung Function Medical Gas Mixture 4 cylinders, their size and construction, type of valve fitted and valve outlet connection is detailed below:

| Cylinder Size | Gas Content (litres) | Cylinder Construction | Valve outlet | Valve Construction |
|---------------|----------------------|-----------------------|--------------------------|--------------------|
| AV | 1500 | Aluminium | BS 341 No.4/ Side Outlet | Brass |
| AK | 6000 | Aluminium | BS 341 No.4/ Side Outlet | Brass |

The cylinder valves are constructed from high tensile brass with a steel spindle fitted with a Nylon 66 insert.

6.6 Instructions for use and handling

All personnel handling Lung Function Medical Gas Mixture 4 cylinders should have adequate knowledge of the properties of the gas, precautions to be taken, actions in the event of an emergency and the correct operating procedures for their installations.

Preparation for Use

Prior to use ensure that:

- The connecting face of the regulator is kept clean and the sealing 'O' ring fitted is in good condition.
- The cylinder valve is opened slowly.
- the cylinder valves and any associated equipment is not lubricated and kept free from oil and grease.

Leaks

Care should be taken to ensure there are no leaks between the regulator connection and the cylinder valve.

The following precautions should be followed:

- Should leaks occur this will usually be evident by a hissing noise.
- Leaks can be found by brushing the suspected area with an approved leak test solution such as 1% Teepol HB7 solution.
- Sealing or jointing compounds must never be used to cure a leak.
- Should a leak occur between the valve outlet and the regulator, depressurise and remove the connector and fit a new 'O' ring seal. Reconnect the cylinder with moderate force only.
- Never use excessive force when connecting equipment to cylinders.

Use of Cylinders

When Lung Function Medical Gas Mixture 4 cylinders are in use ensure that they are:

- Handled with care and not knocked violently or allowed to fall.
- Only be moved with the appropriate size and type of trolley or handling device.
- Firmly secured to a suitable cylinder support.
- Only be used for medical purposes.
- Not used in the vicinity of persons smoking or near naked lights

After use the Lung Function Medical Gas Mixture 4 cylinder valves should be closed using moderate force only.

When the cylinder is empty ensure that:

- The cylinder valve is closed.
- The empty cylinder is immediately returned to the cylinder store for return to BOC.

7 MARKETING AUTHORISATION HOLDER

BOC Ltd

Forge
43 Church Street West,
Woking,
Surrey,
GU21 6HT,
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00735/0012R

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

Date First Granted: 20 March 1991
Date of Renewal: 14 October 1998

10 DATE OF REVISION OF THE TEXT

04/09/2023