SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lung Function Medical Gas Mixture 3

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lung Function Medical Gas Mixture 3 is a medicinal gas mixture of Carbon Monoxide, Helium, Oxygen and Nitrogen. .

The mixture specification is as follows:

Carbon Monoxide	0.28 % +/- 0.03 %
Helium	9.00 % +/- 0.50%
Oxygen	19.00 % +/- 1.00%
Nitrogen	71.72 % +/- 1.53%

3 PHARMACEUTICAL FORM

Medicinal gas, compressed

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Lung Function Medical Gas Mixture 3 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 3 is administered through the lungs by inhalation through volumetric metering and absorption analysis devices. It may be administered by mask.

4.3 Contraindications

There are no contraindications for the use of Lung Function Medical Gas Mixture 3 in any age group.

The use and dosage of Lung Function Medical Gas Mixture 3 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.

4.4 Special warnings and precautions for use

Lung Function Medical Gas Mixture 3 is used for diagnostic and research purposes. The mixture contains carbon monoxide which is toxic, and not more than a few full breaths should be taken because of its great affinity for haemoglobin.

Care is needed with the use and handling of Lung Function Medical Gas Mixture 3 cylinders (see section 6.6).

4.5 Interaction with other medicinal products and other forms of interaction

None Applicable

4.6 Fertility, pregnancy and lactation

Lung Function Medical Gas Mixture 3 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 3 does not affect 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

Lung Function Medical Gas Mixture 3 can be lethal if administered for more than 30 minutes and the amount administered must be controlled by the investigator.

2000 ppm (0.20%) Carbon Monoxide can cause unconsciousness due to poisoning after 30 minutes at rest or 10 minutes of exertion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmcotherapy Group- Other respiratory products

ATC CODE – R07AX

The characteristics of Carbon Monoxide are:

- odourless colourless gas
- Molecular weight 28.00
- Boiling point -192^0C (at 1 bar(g))
- Density 1.165 kg/m^3 (at 15^0C)

The characteristics of Helium are:

- Inert, odourless, colourless gas
- Molecular weight 4.00
- Boiling point -269^0C (at 1 bar(g))
- Density 0.169 kg/m3 (at 15^0C)

Helium has no physiological activity and will not support life.

The characteristics of Oxygen are:

- Odourless, colourless gas
- Molecular weight 32.00
- Boiling point -183.1^{0}C (at 1 bar(g))
- Density 1.355 kg/m3 (at 15^{0}C)

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

The characteristics of Nitrogen are:

- Odourless, inert, colourless gas
- Molecular weight 28.00
- Boiling point -196^{0}C (at 1 bar(g))
- Density 1.185 kg/m3 (at 15^{0}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

The current published toxico-pharmacological data indicates that Lung Function Medical Gas Mixture 3 will not be harmful to humans when administered using approved procedures associated with approved lung function testing equipment.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

Lung Function Medical Gas Mixture 3 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 3 cylinders should be:

- stored in a designated under cover medicinal gas cylinder storage area which should be preferably inside, kept dry and clean and not subjected to extremes of heat or cold.
- not stored near stocks of combustible materials or near sources of heat.
- used in strict rotation.
- stored vertically.
- stored separately from industrial and other non-medical cylinders.
- full and empty cylinder should be stored separately
- 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 3 Cylinder and Valve Details

All cylinders used for the storage of Lung Function Medical Gas Mixture 3 cylinders are manufactured from aluminium with a designed working pressure of at least 150 bar(g).

The cylinder valves are constructed from high tensile brass with a steel spindle fitted with a Nylon 6.6 insert

A summary of Lung Function Medical Gas Mixture 3 cylinders, their size and construction, type of valve fitted and valve outlet pressure is detailed below:

Cylinder Size	Water Capacity (litres)	Gas Content (litres)	Cylinder Construction	Valve Outlet Connection	Cylinder Pressure bar(g)
AV	10.0	1500	Aluminium	BS 341 No.4 Side Outlet	150
AK	40.0	6000	Aluminium	BS 341 No.4 Side Outlet	150

6.6 Special precautions for disposal

General

All personnel handling Lung Function Medical Gas Mixture 3 medical gas cylinders should have adequate knowledge of the:

- properties of the gas
- precautions to be taken when storing, handling and using the cylinders,
- actions to be taken in the event of an emergency,
- correct operating procedures for their use.

Preparation for Use

Prior to using Lung Function Medical Gas Mixture 3 cylinders, ensure that:

- an appropriate medical gas regulator with a BS 341 No.4 inlet connector (with a design pressure of at least 150 bar(g)) is fitted
- the connecting face on the regulator is clean and the 'O' ring fitted is in good condition.
- the cylinder valve is opened slowly
- the cylinder valves and any associated equipment used to deliver the gas to the patient is not lubricated and kept free from oil and grease.

Where moisturising creams are required for use with the face mask, only an approved cream should be used and under no circumstances should oil based creams be used.

Testing for Leaks

Having connected the regulator to the Lung Function Medical Gas Mixture 3 cylinder check the connections for leaks using the following procedure:

- 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.
- Should a leak occur between the valve outlet and the regulator, depressurise and remove the regulator and fit a new 'O' ring. Reconnect the regulator to the valve with moderate force only. If the leak persists, fit a replacement regulator.
- Sealing or joining compounds must never be used to cure a leak.
- Never use excessive force when connecting equipment to cylinders.

Use of Cylinders

When Lung Function Medical Gas Mixture 3 cylinders are in use ensure that they are:

- handled with care and not knocked violently or allowed to fall.
- only moved with the appropriate size and type of trolley or handling device.

- firmly secured to a suitable cylinder support when in use.
- only used for medicinal purposes.
- not used in the vicinity of persons smoking or near naked lights.

After use cylinder valves should be closed using moderate force only and the pressure in the regulator released.

When the Lung Function Medical Gas Mixture 3 cylinder is empty ensure that:

- the cylinder valves is closed using moderate force only and the pressure in the regulator or tailpipe released.
- the valve outlet cap, where fitted, is replaced
- the empty cylinders are immediately returned to the empty 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(S)

PL 00735/0011R

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/03/2017

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20/10/2022