BOC
A Member of The Linde Group

Lung Function medical gas mixture 3.

Essential safety information.

BOC: Living healthcare

Lung Function medical gas mixture 3

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 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

Pharmacotherapy group- Other Respiratory products
ATC CODE – R07AX

The characteristics of carbon monoxide are:
odourless, colourless gas

molecular weight	28.00
boiling point	-192°C (at 1bar(g))
density	1.165kg/m^3 (at 15°C).

The characteristics of helium are:
inert, odourless, colourless gas

molecular weight	4.00
boiling point	-269°C (at 1bar(g))
density	0.169kg/m^3 (at 15°C).

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°C (at 1bar(g))
density	1.355kg/m^3 (at 15°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°C (at 1bar(g))
density	1.185kg/m^3 (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

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 cylinders should be stored separately.
- Segregate medical cylinders containing different gases within the store.
- Emergency services should be advised of the location of the cylinder store.

6.5 Nature and contents of container

All cylinders used for the storage of Lung Function medical gas mixture 3 are manufactured from aluminium with a designed working pressure of at least 150bar(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	1,500	Aluminium	BS 341 No.4 Side outlet	150
AK	40.0	6,000	Aluminium	BS 341 No.4 Side outlet	150

6.6 Special precautions for disposal and other handling

All personnel handling Lung Function medical gas mixture 3 cylinders should have adequate knowledge of:

- properties of the gas
- correct operating procedures for the cylinder
- precautions and actions to be taken in the event of an emergency.

Preparation for use

To prepare the cylinder for use:

- remove the tamper evident seal and the valve outlet protection cap. Ensure cap where fitted, is retained
- ensure that an appropriate medical gas regulator with a BS 341 No.4 inlet connector (with a design pressure of at least 150bar(g)) is fitted
- do not remove and discard any batch labels fitted to the cylinder
- ensure the connecting face on the regulator is clean and the 'O' ring fitted is in good condition
- connect the regulator, using moderate force only and connect the tubing to the regulator/flowmeter outlet
- only the appropriate regulator should be used for the particular gas concerned
- open the cylinder valve slowly and check for any leak.

Leaks

Having connected the regulator or manifold yoke to the cylinder check the connections for leaks using the following procedure:

- should leaks occur this will usually be evident by a hissing noise
- should a leak occur between the valve outlet and the regulator or manifold yoke, depressurise and remove the fitting and fit an approved 'O' ring
- reconnect the fitting to the valve with moderate force only, fitting a replacement regulator or manifold tailpipe as required
- sealing or jointing compounds must never be used to cure a leak
- if leak persists, label cylinder and return to BOC.

Use of cylinders

When Lung Function medical gas mixture 3 cylinders are in use ensure that they are:

- only used for medicinal purposes
- turned off, when not in use, using only moderate force to close the valve
- only moved with the appropriate size and type of trolley or handling device
- handled with care and not knocked violently or allowed to fall
- firmly secured to a suitable cylinder support when in use
- not allowed to have any markings, labels or batch labels obscured or removed
- not used in the vicinity of persons smoking or near naked lights.

After use

When the Lung Function medical gas mixture 3 cylinder is empty ensure that the:

- cylinder valve is closed using moderate force only and the pressure in the regulator or tailpipe released
- valve outlet cap, where fitted, is replaced
- empty cylinders are immediately returned to the empty cylinder store for return to BOC.

7. Marketing authorisation holder

BOC Ltd
The Priestley Centre
10 Priestley Road
The Surrey Research Park
GUILDFORD
Surrey, GU2 7XY

8. Marketing authorisation number(s

PL 00735/0011R.

9. Date of first authorisation/renewal of the authorisation

Date first granted: 15/03/2017.

10. Date of revision of the text

15/03/2017

11. Dosimetry (if applicable

Not applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)

Not applicable.

Supply classification status

1. Supply classification status

Pharmacy.

Additional Safety Information

1. Contact information

BOC telephone number to be used in the event of an emergency
UK 0800 111 333

2. Hazards

Classification labelling and packaging regulations

Warning.
Contains gas under pressure; may explode if heated (H280).
Protect from sunlight: store in a well-ventilated place (P410 + P403).

Dangerous Preparations Directive

Keep out of the reach of children (S2).

Additional safety statements

- No smoking or naked flames near medical gas cylinders.
- Use no oil or grease.
- Keep away from extremes of heat and combustible material.
- Store cylinders under cover in a clean, dry and well ventilated area.

Lung Function medical gas mixture 3 is supplied as a compressed gas in a high pressure cylinder. Cylinders may explode if subjected to extremely high temperatures (if involved in a fire).

3. Fire fighting measures

If Lung Function medical gas mixture 3 cylinders are involved in a fire:

- if it is safe to move the cylinders,
  - close cylinder valve to stop flow of product
  - move cylinders away from source of heat.
- if it is not safe to move the cylinders,
  - cool with water from a protected position.

All types of fire extinguishers may be used when dealing with a fire involving Lung Function medical gas mixture 3 cylinders.

Fire fighters should use self-contained breathing apparatus when dealing with a fire in which Lung Function medical gas mixture 3 cylinders are involved.

4. Accidental release measures

If a large volume of Lung Function medical gas mixture 3 is released if it is safe to do so, you should close the cylinder valve and where possible, eliminate all sources of ignition.

If release continues evacuate the area and ensure that the affected area is adequately ventilated before re-entry.

Self-contained breathing apparatus is required to be used if Lung Function medical gas mixture 3 is released into a confined area without adequate ventilation.

5. Exposure controls

When using Lung Function medical gas mixture 3 ensure adequate ventilation of the Lung Function test area.

Caution: Long term exposure to Lung Function medical gas mixture 3, inhaled for periods longer than those indicated for clinical use (in excess of 15 minutes) may cause the user to become unconscious and may cause harm to the unborn foetus (due to the carbon monoxide component of the gas).

The UK exposure limit for carbon monoxide (as defined in EH40/2005) specifies the Long Term Exposure Level (TWA over 8 hours) should not exceed 30 ppm.

A Short Term Exposure level (15- minute reference period) should not exceed 200 ppm.

6. Disposal considerations

It is recommended that Lung Function medical gas mixture 3 cylinders should not be vented after use – they should be returned to BOC with any residual gas where they will be vented before refilling in a safe environment.

If, for safety reasons, a cylinder is required to be vented after use, the gas should be vented to atmosphere in a well ventilated area.

Contact BOC if further guidance on venting cylinders is required.

7. Transport of cylinders

When Lung Function medical gas mixture 3 cylinders are required to be transported, ensure that the cylinders are:

- located in a compartment separated from the driver
- adequately restrained
- not leaking and have their valves closed.

The vehicle must be adequately ventilated. Ensure the driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.

It is advisable to provide the driver with written instructions that detail the actions to be taken in the event of an accident or emergency.

Cylinders should be removed from the vehicle as soon as possible.

8. Transport information

UN number	UN1956 compressed gas N.O.S.
Material:	Class 2
Labels	2.2
Hazard identification number	20
Emergency Action Code	2TE
Tunnel Restriction Code	E
Transport category	3

Notes

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Notes

Notes

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HLC/606580/UKS/BAMC/0517