

Medical Gas Data Sheet (MGDS) 9% helium/35% oxygen/ nitrogen medical gas mixture

Essential safety information



9% helium/35% oxygen/nitrogen medical gas mixture SPC

1. Name of the medicinal product

9% helium/35% oxygen/nitrogen medical gas mixture.

2. Qualitative and quantitative composition

9% helium/35% oxygen/nitrogen medical gas mixture is a medicinal gas mixture of helium, oxygen and nitrogen.

The mixture specification is as follows:

helium:	9%+/- 0.50%
oxygen:	35% +/- 1%
nitrogen:	balance.

Maximum impurity levels:

carbon monoxide:	5vpm
carbon dioxide:	300vpm
moisture:	50vpm.

The medical oxygen specification complies with the current European Pharmacopoeia monograph (0417). The nitrogen specification complies with the current European Pharmacopoeia monograph (1247). The helium specification complies with the current European Pharmacopoeia monograph (2155).

3. Pharmaceutical form

Medicinal gas, compressed.

4. Clinical particulars

4.1 Therapeutic indications

9% helium/35% oxygen/nitrogen medical gas mixture is used for pulmonary physiology.

Indications for 9% helium/35% oxygen/nitrogen medical gas mixture are dictated by the clinical investigator.

4.2 Posology and method of administration

9% helium/35% oxygen/nitrogen medical gas mixture is administered through the lungs by inhalation usually through volumetric metering and absorption analysis devices. It may be administered by means of a tent.

4.3 Contraindications

There are no contraindications for the use of 9% helium/35% oxygen/nitrogen medical gas mixture in any age group.

The use and dosage of 9% helium/35% oxygen/nitrogen medical gas mixture is determined by the respiratory function test being applied.

9% helium/35% oxygen/nitrogen medical gas mixture should not normally be used with elderly, chronic bronchitic patients as the oxygen concentration exceeds 35%.

- 4.4 Special warnings and precautions for use** Where the patient has been exposed to agents which are toxic to the lungs, such as Paraquat, the use of gases containing more than 21% oxygen should be avoided.
- 4.5 Interaction with other medicinal products and other forms of interaction** The use of higher levels of oxygen can increase the risk of pulmonary toxicity in patients who have been administered Bleomycin, Amiodarone and Nitrofurantoin or similar antibiotics. In these cases 9% helium/35% oxygen/nitrogen medical gas mixture should be administered with caution and at levels kept as low as possible.
- 4.6 Pregnancy and lactation** 9% helium/35% oxygen/nitrogen medical gas mixture is not contraindicated in pregnancy and is unlikely to influence lactation.
- 4.7 Effects on ability to drive and use machines** In normal circumstances, 9% helium/35% oxygen/nitrogen medical gas mixture does not affect ability to drive or to operate machinery.
- 4.8 Undesirable effects** High barometric pressures, above 3bar(g), may produce convulsions due to oxygen content, if continued for more than a few hours.
- 4.9 Overdose** None applicable.
- 5. Pharmacological properties** Pharmacotherapeutic group – medical gas.
ATC Code - V03AN.
- 5.1 Pharmacodynamic properties** Helium - The characteristics of helium are:
- odourless, colourless gas
 - molecular weight 4
 - boiling point -269°C (at 1bar(g))
 - density 0.169kg/m³ (at 15°C).
- Helium has no physiological activity and will not support life.
- Oxygen - The characteristics of oxygen are:
- odourless, colourless gas
 - molecular weight 32
 - boiling point -183.1°C (at 1bar(g))
 - density 1.355kg/m³ (at 15°C).
- Oxygen is present in the atmosphere at 21% and is an absolute necessity for life.
- Nitrogen - The characteristics of nitrogen are:
- odourless, colourless gas
 - molecular weight 28
 - boiling point -196°C (at 1bar(g))
 - density 1.185kg/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** Helium has a low co-efficient of solubility and high rate of diffusion compared with nitrogen. It is completely inert and non-toxic. When helium replaces the nitrogen in air, the specific gravity of the resultant helium mixture will flow through bronchi more easily than air. In patients with respiratory obstruction, therefore, more oxygen may be presented to the alveolus for the same ventilatory effort. The absorption of helium from alveoli is very slow. Inhalation of helium may be used to prevent atelectasis.
- The uptake of oxygen by the blood in the lungs and discharge to the tissues is determined by the oxygen dissociation curve. The characteristic sigmoid shape ensures that, at tensions between 40 and 15mm Hg, the oxygen carried in the blood from the lungs can be readily given up to the tissues.
- The uptake from the lungs is rapid because blood flow through the capillaries, where exchange takes place, occurs in about 0.5 seconds. The uptake of oxygen is favoured by the simultaneous loss of carbon dioxide which is then excreted in the expired air. Conversely the entry of carbon dioxide into the blood from the

tissues facilitates oxygen transfer to the cells.

At rest, mixed venous blood returning to the lungs contains 13-14ml of oxygen per 100ml, but with severe exercise, the oxygen content may fall to 3-4ml. In very active tissue, almost complete extraction occurs.

Nitrogen is soluble in fat but saturates slowly. Under pressure, nitrogen will form bubbles in tissues and blood.

5.3 Preclinical safety data None stated.

6. Pharmaceutical particulars

6.1 List of excipients None.

6.2 Incompatibilities The constituent gases of 9% helium/35% oxygen/nitrogen medical gas mixture are chemically inactive and will not normally react with other compounds at normal temperatures.

However, the medical oxygen component of 9% helium/35% oxygen/nitrogen medical gas mixture strongly supports combustion and will cause substances to burn, including some materials that will not normally burn in air. It is highly dangerous in the presence of oils, greases, tarry substances and many plastics due to the risk of spontaneous combustion in the presence of medical oxygen in relatively high concentrations.

6.3 Shelf life 36 months.

6.4 Special precautions for storage 9% helium/35% oxygen/nitrogen medical gas mixture cylinders should be:

- stored under cover, preferably inside, kept dry and clean, and not subjected to extremes of heat or cold and away from stocks of combustible material
- stored separately from industrial and other non-medical cylinders
- stored to maintain separation between full and empty cylinders
- used in strict rotation so that cylinders with the earliest filling date are used first
- stored separately from other medical cylinders within the store.

Warning notices prohibiting smoking and naked lights must be posted clearly in the cylinder storage area and the emergency services should be advised of the location of the cylinder store.

Care is needed when handling and using 9% helium/35% oxygen/nitrogen medical gas mixture cylinders.

6.5 Nature and contents of container 9% helium/35% oxygen/nitrogen medical gas mixture cylinder and valve details.

All cylinders used for the storage of 9% helium/35% oxygen/nitrogen medical gas mixture are manufactured from aluminium with a designed working pressure of at least 150bar(g). These cylinders are designed to be used with a pressure regulator.

A summary of 9% helium/35% oxygen/nitrogen medical gas mixture cylinders, their size and construction, type of valve fitted and valve outlet connection is detailed below:

Cylinder details			Valve details	
Size	Gas content (litres)	Cylinder construction	Valve outlet	Valve construction
AV	1,500	Aluminium	BS 341 No.4 Side outlet	Brass
L	6,000	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 6.6 insert.

6.6 Special precautions for disposal and other handling	<p>All personnel handling 9% helium/35% oxygen/nitrogen medical gas mixture cylinders should have adequate knowledge of</p> <ul style="list-style-type: none"> • 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	<p>To prepare the cylinder for use:</p> <ul style="list-style-type: none"> • remove the tamper evident seal and the valve outlet protection cap. Ensure the cap, where fitted, is retained so that it can be refitted after use • do not remove and discard any batch labels fitted to the cylinder • ensure that an appropriate regulator is selected for connection to the cylinder • ensure the connecting face on the regulator is clean and the sealing washer fitted is in good condition • ensure that the cylinder valves and any associated equipment is not lubricated and kept free from oil and grease • 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 leaks.
Leaks	<p>Having connected the regulator or manifold yoke to the cylinder, check the connections for leaks using the following procedure:</p> <ul style="list-style-type: none"> • 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 sealing washer. 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	<p>When 9% helium/35% oxygen/nitrogen medical gas mixture cylinders are in use, ensure that they are:</p> <ul style="list-style-type: none"> • 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	<p>When the 9% helium/35% oxygen/nitrogen medical gas mixture cylinders are empty, ensure that the:</p> <ul style="list-style-type: none"> • cylinder valves are 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 an empty cylinder storage area for return to BOC.3 •
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 00735/5015R.
9. Date of first authorisation/renewal of the authorisation	<p>Date first granted: 01/09/1972.</p> <p>Date of renewal: 27/03/1996.</p>
10. Date of revision of the text	23/04/2013
11. Dosimetry (if applicable)	Not applicable.
12. Instructions for preparation of radiopharmaceuticals (if applicable)	Not applicable.

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



Danger.

May cause or intensify fire; oxidiser (H270).

Contains gas under pressure; may explode if heated (H280).

Keep/Store away from clothing, hydrocarbons and combustible materials (P220).

Keep reduction valves free from grease and oil (P244).

In case of fire: stop leak if safe to do so (P370 + P376).

Protect from sunlight: store in a well-ventilated place P410 + P403).

Dangerous Preparations Directive



Contact with combustible material may cause fire (R8).

Keep out of the reach of children (S2).

Keep away from combustible material (S17).

Label statements

- Contact with combustible material may cause fire
- No smoking or naked flames near medical oxygen 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

Medical oxygen 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).

Medical oxygen is a non-flammable gas but is a very strong oxidant. It will strongly support and intensify combustion.

It may react violently with combustible materials such as oils and grease.

3. Fire fighting measures If medical oxygen cylinders are involved in a fire:

- if it is safe to move the cylinders,
 - close cylinder valve to stop the 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 medical oxygen cylinders.

No special protective equipment for fire fighters is required. There are no hazardous combustion products released from the gas.

4. Accidental release measures

If a large volume of medical oxygen is released, if safe to do so, you should:

- close the cylinder valve
- where possible, isolate 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 not required to be used if oxygen is released in a confined area.

5. Exposure controls

When using medical oxygen cylinders ensure adequate ventilation. If clothing becomes impregnated with oxygen (due to a leak), keep away from sources of ignition or open flames. Clothing impregnated with oxygen should be ventilated in fresh air for a minimum of 15 minutes.

6. Disposal considerations

It is recommended that medical oxygen 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 medical oxygen 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. Use of cylinders in transit – advice to patient/carer

If you need to use medical oxygen within a vehicle, you are advised to:

- prohibit smoking in the vehicle
- only carry the minimum number of cylinders to provide sufficient gas for patient use during the journey/activity
- ensure all cylinders are adequately restrained
- keep cylinder valves closed when not in use
- avoid using the cylinder when the vehicle is being refuelled
- set the ventilation system to fresh air or open a window to provide adequate ventilation and to prevent oxygen enrichment within the vehicle
- avoid leaving cylinders unattended in a vehicle. Unless the vehicle is specifically designed to carry medical oxygen cylinders, they should be removed from the vehicle overnight.

9. Transport information

UN number	UN1072 oxygen, compressed
Material	Class 2
Labels	2.2, 5.1
Hazard identification number	25
Emergency Action Code	2s
Tunnel Restriction Code	E
Transport category	3

BOC Healthcare

Customer Service Centre, Priestley Road, Worsley, Manchester M28 2UT

Tel 0800 111 333, Fax 0800 111 555, bohealthcare-uk@boc.com, www.bohealthcare.co.uk

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