

# 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% +/- 1.5%
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.

9% Helium/ 35% Oxygen / Nitrogen Medical Gas Mixture is non flammable but strongly supports combustion and should not be used near sources of ignition.

Smoking should be prohibited when using 9% Helium/ 35% Oxygen / Nitrogen Medical Gas Mixture.

Under no circumstances should oils or grease be used to lubricate any part of the 9% Helium/ 35% Oxygen / Nitrogen Medical Gas Mixture cylinder or the associated equipment used to deliver the gas to the patient.

Where moisturising creams are required for use with a facemask or in nasal passages, oil based creams should not be used.

Check that hands are clean and free from any oils or grease.

Where alcohol gels are used to control microbiological cross-contamination ensure that all alcohol has evaporated before handling 9% Helium/ 35% Oxygen / Nitrogen Medical Gas Mixture cylinders or equipment.

Care is needed in the handling and use of 9% Helium/ 35% Oxygen /Nitrogen Medical Gas Mixture cylinders.

**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.

### 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](http://www.mhra.gov.uk/yellowcard)

**4.9 Overdose** None applicable.

## 5. Pharmacological properties

**5.1 Pharmacodynamic properties** Pharmacotherapeutic group – medical gas.

ATC Code - V03AN

Helium - The characteristics of helium are:

- odourless, colourless gas
  - molecular weight 4
  - boiling point -269°C (at 1bar(g))
- density 0.169kg/m<sup>3</sup> (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/m<sup>3</sup> (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/m<sup>3</sup> (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

### 6.6 Special precautions for disposal and other handling

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

All personnel handling 9% helium/35% oxygen/nitrogen medical gas mixture 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 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**

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 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**

When 9% helium/35% oxygen/nitrogen medical gas mixture cylinders are in use, ensure that they are:

- only used for medicinal purposes

**After use**

- 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.

When the 9% helium/35% oxygen/nitrogen medical gas mixture cylinders are empty, ensure that the:

- 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** Date first granted: 01/09/1972.  
Date of renewal: 27/03/1996.

**11. Dosimetry (if applicable)** 25/05/2016

**12. Instructions for preparation of radiopharmaceuticals (if applicable)** Not applicable.

# Notes

# 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**

- No smoking or naked flames near medical gas mixture 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

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

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

No special protective equipment for fire fighters is required. If clothing becomes impregnated with this mixture (due to a leak), keep away from sources of ignition or open flames. Clothing impregnated with this mixture should be ventilated in fresh air for a minimum of 15 minutes. There are no hazardous combustion products released from the gas.

If a large volume of 9% helium/35% oxygen/nitrogen medical gas mixture is

**4. Accidental release** released, if it is safe to do so, you should:

**measures**

- close cylinder valve
- 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 not required to be used if 9% helium/ 35% oxygen/nitrogen medical gas mixture is released in a confined area.
- If clothing becomes impregnated with this mixture (due to a leak), keep away from sources of ignition or open flames.
- Clothing impregnated with this mixture should be ventilated in fresh air for a minimum of 15 minutes.

**5. Exposure controls** When using 9% helium/35% oxygen/nitrogen medical gas mixture cylinders, ensure adequate ventilation.

**6. Disposal considerations** It is recommended that 9% helium/35% oxygen/nitrogen medical gas mixture 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 9% helium/35% oxygen/nitrogen medical gas mixture 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	UN3156 Compressed gas, oxidizing, N.O.S (oxygen, nitrogen)
Material	Class 2
Labels	2.2, 5.1
Hazard identification number	25
Emergency Action Code	2s
Tunnel Restriction Code	E
Transport category	3

# Notes

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**BOC Healthcare**

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