

Medical helium



Summary of Product Characteristics (SPC)

1. Name of the medicinal product	Medical Helium.
2. Qualitative and quantitative composition	The specification for Medical Helium is: Helium 99.5%
3. Pharmaceutical form	Medicinal gas, compressed.
4. Clinical particulars	
4.1 Therapeutic indications	Because of its low density helium flows through an orifice much more easily than other medical gases. Helium is used with a least 21% oxygen in the following circumstances: <ul style="list-style-type: none"> • To assist the flow of oxygen into the alveoli of patients with severe respiratory obstruction • To prevent atelectasis • In various concentrations, in conjunction with air or oxygen, for gas transfer lung function tests.
4.2 Posology and method of administration	There is no distinction generally between the use of helium in different age groups. In its role as a carrier for oxygen, helium is administered through the lungs by inhalation with 21% oxygen or higher concentrations by mask or endotracheal tube.
4.3 Contraindications	None applicable.
4.4 Special warnings and precautions for use	Helium should never be used with less than 21% oxygen. Helium will diffuse through rubber tubing. Care is needed in the use and handling of medical helium (see section 6.6).
4.5 Interaction with other medicinal products and other forms of interaction	None applicable

4.6 Pregnancy and lactation	Medical Helium does not adversely affect pregnancy and lactation.
4.7 Effects on ability to drive and use machines	In normal circumstances, Medical Helium does not affect ability to drive or to operate machinery.
4.8 Undesirable effects	With helium, the only undesirable effect will result from less than 21% oxygen, being given with the helium when, with decreasing oxygen levels, asphyxia will result. 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	Other than the condition detailed in 4.8 'Undesirable Effects', there are no other overdose issues with Medical Helium.
5. Pharmacological properties	
5.1 Pharmacodynamic properties	Pharmacotherapeutic Group – Medical gas ATC Code – V03AN03 The characteristics of helium are: <ul style="list-style-type: none"> • inert, colourless gas • Molecular weight 4.00 • 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.
5.2 Pharmacokinetic properties	Helium has a low coefficient 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/oxygen (79:21) mixture is 341 (compared with air at 1000). This mixture flows through bronchi three times more easily than air. In patients with respiratory obstruction, therefore, more oxygen may be presented to the alveoli for the same ventilatory effort. The absorption of helium from alveoli is very slow. Inhalation of helium may be used to prevent atelectasis.
5.3 Preclinical safety data	The current published toxico-pharmacological data indicates that Helium will not be harmful to humans when administered with at least 21% Oxygen.
6. Pharmaceutical particulars	
6.1 List of excipients	None
6.2 Incompatibilities	Medical Helium 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** Medical Helium cylinders should be:
- stored in a designated under cover medical 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
 - medical cylinders containing different gases should be segregated 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
 - cylinders must not be repainted, have any markings obscured or labels removed
 - protected from theft.

- 6.5 Nature and contents of container** **Medical Helium Cylinder and Valve Details**
Medical Helium cylinders are manufactured from steel with a design working pressure of at least 137 bar(g) at 15°C. The cylinder valves are constructed from high tensile brass with a steel spindle fitted with a Nylon 6.6 insert. A summary of Medical Helium cylinders, their size, capacity and construction, type of valve fitted and valve outlet pressure is detailed below:

Cylinder Size	Water capacity (litres)	Gas content (litres)	Valve Outlet Connection	Cylinder Pressure bar(g)
F	9.3	1200	BS 341 No.3 Top Outlet fitted with MPR device	137

- 6.6 Special precautions for disposal** **General**
All personnel handling Medical Helium 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 Medical Helium cylinders, ensure that:

- an appropriate medical gas regulator (with a design pressure of at least 137 bar(g)) is fitted. A regulator with BS 341 No.3 inlet connector must be used
- the connecting face on the regulator is clean and the 'O' ring / seal 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.

Leaks

Having connected the regulator to the Medical Helium 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 Medical Helium 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 Medical Helium cylinder is empty ensure that:

- the cylinder valve 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.
The Priestley Centre
10 Priestley Road
The Surrey Research Park
GUILDFORD
Surrey, GU2 7XY.

- 8. Marketing authorisation number(s)** PL 00735 / 5008R

- 9. Date of first authorisation/renewal of the authorisation** 21/11/2016.

- 10. Date of revision of the text** 21/11/2016.

- 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 11 333

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

Helium 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 Helium 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 cylinder,
 - cool with water from a protected position.

All types of fire extinguishers may be used to extinguish fires involving Helium.

Fire fighters should use self-contained breathing apparatus when dealing with a fire in which Medical Helium cylinders are involved.

4. Accidental release measures If a large volume of Helium is released you should:

- Close cylinder valve.

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 Helium is released into a confined area without adequate ventilation.

5. Disposal considerations It is recommended that medical helium cylinders should not be vented after use – they should be returned to BOC, where they will be vented before refilling in a safe environment.

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

Contact BOC if further guidance on venting cylinders is required.

6. Transport of cylinders When Helium 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.

7. Transport information

UN number	UN1046
Material	Class 2 Classification Code 1A
Labels	2.2
Hazard identification number	20
Emergency Action Code	2T
Transport category	3

BOC Healthcare

The Priestley Centre, 10 Priestley Road, The Surrey Research Park, Guildford, Surrey GU2 7XY, United Kingdom
Tel +44 1483 579 857, Fax +44 1483 505 211, www.BOOnline.co.uk

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