

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Medical Helium

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Medical Helium Cylinders are supplied to the following specification:
Helium 99.5%

The Medical Helium cylinder specification complies with the current European Pharmacopoeia monograph (2155).

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:

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 age groups. In its role as a carrier for oxygen, helium is administered through the lungs by inhalation with 21% or higher concentrations of oxygen by mask or endotracheal tube. Cylinders should only be used in conjunction with medical helium gas pressure regulators, although medical oxygen gas pressure regulators may be used on the F-size helium cylinders.

4.3 Contraindications

Not 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 handling and use of medical helium gas cylinders.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Fertility, pregnancy and lactation

Helium does not adversely affect pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Not applicable.

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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

As detailed in *section 4.8, Undesirable effects* above.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Medical Gas
ATC Code: V03AN03

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

- Molecular weight 4.00
- Boiling point -269°C (at 1 bar)
- Density 1.169kg/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

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Medical Helium is highly dangerous when in contact with oils, gases, tarry substances and many plastics due to the risk of spontaneous combustion with high pressure gases.

6.3 Shelf life

1 year

6.4 Special precautions for storage

Medical Helium 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
- F size cylinders and larger should be stored vertically.

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 Medical Helium cylinders.

6.5 Nature and contents of container

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

Cylinders

Medical Helium Cylinder and Valve Details

All cylinders used for the supply of Medical Helium are manufactured from steel with a design working pressure of at least 137 bar (g). The body and shoulder of the cylinders are coloured brown.

Cylinder Valves

All Medical Helium cylinders are fitted with valves with outlet connections that conform to BS 341 (5/8" BSP F). 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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Care is needed in the handling and use of medical helium gas cylinders. Helium is considerably lighter than air, non-toxic, inert and will not support life. At high concentrations it acts as an asphyxiant by displacement of air. Symptoms of asphyxiation include rapid and gasping respiration, rapid fatigue, nausea and vomiting and cyanosis and may lead to loss of consciousness and death from anoxia. Helium should never be inhaled except in approved mixtures with other gases and under authorised circumstances.

General

All personnel handling Medical Helium gas cylinders should have adequate knowledge of the:

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

To prepare the cylinder for use:

- remove the tamper evident seal and the valve outlet protection cap. Ensure the cap is retained so that it can be refitted after use.
- 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.
- 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.
- Never use excessive force when connecting equipment to cylinders.

Use of Cylinders

When Medical Helium 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 used in the vicinity of persons smoking or near naked lights.
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After use

When Medical Helium cylinders are 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 Gases Ireland Limited
J F Kennedy Drive
Bluebell
Dublin 12

8 MARKETING AUTHORISATION NUMBER

PA0208/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1980

Date of last renewal: 01 April 2010

10 DATE OF REVISION OF THE TEXT

November 2015

11 DOSIMETRY

Not applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable