SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Medical Helium

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Helium BP 1988 100%

3 PHARMACEUTICAL FORM

Inhalation gas

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

To prevent atelectasis and to assist oxygen flow into lung alveoli in cases of severe respiratory obstruction. Also for use in respiratory function tests.

4.2 Posology and method of administration

For respiratory use at concentrations of 79% or less

4.3 Contraindications

None

4.4 Special warnings and precautions for use

Helium should never be given with less than 21% oxygen and should never be inhaled on its own.

4.5 Interaction with other medicinal products and other forms of interaction

None

4.6 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

Undesirable effects are only observed if helium is used with less than 21% oxygen (see 4.9).

4.9 Overdose

Inhalation of helium alone or with less than 21% oxygen may lead to asphyxiation as, at high concentrations, helium displaces 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.

If inhalation of helium ceases in time these effects may be reversed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Helium is an inert, odourless, colourless gas with molecular weight 4.00, a boiling point of -269°C (at 1 bar) and a density of 0.169 kg/m^3 (at 15°C and 1013mb).

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. 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.

5.3 Preclinical safety data

There are no additional data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

Helium will diffuse through rubber tubing.

6.3 Shelf life

Five years.

6.4 Special precautions for storage

Cylinders should be kept out of the reach of children.

Helium is non-flammable and does not support combustion.

The normal precautions required in the storage of medical gas cylinders as described below are applicable.

- Cylinders should be stored under cover, preferably inside, kept dry and clean and not subjected to extremes of heat or cold.
- Cylinders should not be stored near stocks of combustible materials or near sources of heat.
- Warning notices prohibiting smoking and naked lights must be posted clearly.
- Emergency services should be advised of the location of the cylinder store.
- Medical cylinders containing different gases should be segregated and identified within the store.
- Full and used cylinders should be stored separately. Full cylinders should be used in strict rotation.
- Cylinders must not be repainted, have any markings obscured or labels removed.
- F size cylinders and larger should be stored vertically E size cylinders and smaller should be stored horizontally.
- Precautions should be taken to protect cylinders from theft

6.5 Nature and contents of container

Helium is supplied in a gas cylinder with valve, suitable for the pressure required for the product.

The types of cylinders normally used are specified in the following table.

Cylinder Size	Water Volume (litres)	Fill Pressure (m^3)	Fill Volume (m^3)	Valve Type (1)
D	2.32	137	0.3	Pin-index
F	9.43	137	1.2	Bullnose 5/8" BSP female
F4	9.43	230	2.0	4bar outlet Schraeder connector

Note: (1) Cylinder valves conform to B5341 (non pin-index index – except the 4bar outlet valves which are proprietary) and BS EN 850:1997 (pin-index)

The cylinders are colour coded as specified in BS 1319 (1976) and ISO 32 (1977). The colour for helium is saddle brown for both body and shoulder.

6.6 Special precautions for disposal

Care is needed in the handling and use of medical helium gas cylinders.

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. N.B. Where the 4bar outlet, Schraeder connector valve is fitted, no additional regulator is necessary.

Preparation for use

1. Cylinder valves should be opened momentarily prior to use to blow any foreign matter out of the outlet
2. Ensure that the connecting face on the yoke, manifold or regulator is clean and the sealing washer or ‘0’ ring where fitted is in good condition.
3. Cylinder valves must be opened slowly.
4. Only the appropriate regulator should be used for the particular gas concerned, (N.B. See note on “F” size cylinders, above). N.B. Where the 4bar outlet, Schraeder connector valve is fitted, no additional regulator is necessary.
5. Pipelines for medical gases should be installed in accordance with the conditions set out in HTM 2022.
6. Cylinder valves and any associated equipment must never be lubricated and must be kept free from oil and grease.

Leaks

1. Should leaks occur this will usually be evident by a hissing noise.
2. Leaks can be found by brushing the suspected area with an approved leak test solution.
3. There are no user serviceable parts associated with these valves, do not attempt to correct any problems with leakage from any part of the valve itself. Label any faulty containers, and return them to Linde Gas for repair.
4. Sealing or jointing compounds must never be used to cure a leak.
5. Never use excessive force when connecting equipment to cylinders.

Use of Cylinders

1. Cylinders should be handled with care and not knocked violently or allowed to fall.
2. Cylinders should only be moved with the appropriate size and type of trolley.
3. When in use cylinders should be firmly secured to a suitable cylinder support.
4. Cylinders containing liquefiable gas must always be used vertically with the valve uppermost.
5. Medical gases must only be used for medicinal purposes.
6. Smoking and naked lights must not be allowed within the vicinity of cylinders or pipeline outlets.
7. After use cylinder valves should be closed using moderate force only and the pressure in the regulator or tailpipe released.
8. When only a small amount of gas remains in a cylinder, the cylinder valve must be closed. It is important to leave a small residual pressure in each cylinder after use, in order to protect the inside of the cylinder from contamination.

9. Immediately return used cylinders to the used cylinder store for return to Linde Gas.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PL 15929/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/03/1998 / 16/04/2003

10 DATE OF REVISION OF THE TEXT

19/07/2010