SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Medical Oxygen 21%/Helium 79%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxygen Ph.Eur. 21% and Helium BP (1988) 79%

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.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

None.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

The gas mixture does not adversely affect pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None.

4.9 Overdose

Not applicable.

Overdose symptoms are only observed if helium is inhaled with less than 21% oxygen.

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.

Oxygen is a colourless, odourless gas with molecular weight 32, a boiling point of -183.1°C (at 1 bar) and a density of 1.355 kg/m^3 (at 15°C and 1013mb).

Oxygen is present in the atmosphere at 21% and is an absolute necessity for life.

21% oxygen/79% helium gas mixture has a specific gravity of 0.34 (at 15°C) and a density of 0.42 kg/m^3 (at 15°C and 1013mb).

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.

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 15 mm 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.

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.

Oxygen is non-flammable but strongly supports combustion (including some materials which do not normally burn in air). It is highly dangerous when in contact with oils, greases, tarry substances and many plastics due to the risk of spontaneous combustion with high pressure gases.

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

Oxygen 21%/Helium 79% 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]
AD 137	2	137	0.3	Integral pressure regulator valve with Schraeder connection
AD 200	2	200	0.4	Integral pressure regulator valve with Schraeder connection
AE4C 137	5	137	0.6	Integral pressure regulator valve with Schraeder connection
AE4C 200	5	200	0.9	Integral pressure regulator valve with Schraeder connection
F	9.43	137	1.2	B341 no. 3
F4	9.43	230	2.0	Integral pressure regulator valve with Schraeder connection
A10C 137	10	137	1.3	Integral pressure regulator valve with Schraeder connection
A10C 200	10	200	1.8	Integral pressure regulator valve with Schraeder connection
A15C137	15	137	1.9	Integral pressure regulator valve with Schraeder connection
A15C200	15	200	2.8	Integral pressure regulator valve with Schraeder connection
A20C 137	20	137	2.6	Integral pressure regulator valve with Schraeder connection
A20C 200	20	200	3.7	Integral pressure regulator valve with Schraeder connection
G	23.6	137	3.0	B341 no. 3
G4	23.6	230	5.0	Integral pressure regulator valve with Schraeder connection
AJ4C 137	50	137	6.5	ISO 5145 no. 26
AJ4C 200	50	200	9.2	ISO 5145 no. 26
J 137	50	137	6.5	ISO 5145 no. 26

J 200	50	200	9.2	ISO 5145 no. 26

Note: (1) Cylinder valve outlets conform to B5341 or ISO 5145 or are integral pressure regulator valves with 4 bar or 4.5 bar regulated outlet valves with a Schraeder connection that conforms to BS 5682.

The cylinders are colour coded, a black body with a white and saddle brown quartered shoulder.

6.6 Special precautions for disposal

Care is needed in the handling and use of oxygen 21%/helium 79% gas cylinders.

Cylinders should only be used in conjunction with medical oxygen gas pressure regulators.

Conversion Chart Using Oxygen Flowmeter	
Req He/O_2 flow rate (LPM)	**Flow meter reading (LPM)**
2	1.1
4	2.2
6	3.3
8	4.4
10	5.6
12	6.7
14	7.8

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. 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 Air Liquide 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 Air Liquide.

7 MARKETING AUTHORISATION HOLDER

Air Liquide Ltd

Station Road

Coleshill

Birmingham

West Midlands

B46 1JY

8 MARKETING AUTHORISATION NUMBER(S)

PL 15929/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19th March 1998/17th April 2003

10 DATE OF REVISION OF THE TEXT

10th September 2007