

HELIOX21 (helium 79%, oxygen 21%, medicinal gas, compressed).

Essential safety information.

HELIOX21 (helium 79%, oxygen 21%, medicinal gas, compressed)

1. Name of the medicinal product HELIOX21 (helium 79%, oxygen 21%, medicinal gas, compressed)

2. Qualitative and quantitative composition HELIOX21 specification is:

Oxygen Ph. Eur	21% +/- 0.5%
Helium Ph. Eur	79% +/- 0.5%

3. Pharmaceutical form Medicinal gas, compressed.

4. Clinical particulars

4.1 Therapeutic indications HELIOX21 is indicated to assist flow of oxygen into the alveoli and to reduce the work of breathing in patients with severe airway obstruction (upper or lower).

4.2 Posology and method of administration HELIOX21 is administered to patients as supplied in a 79% helium/21% oxygen ratio, but can also be administered with supplemental oxygen at the physician's discretion according to patients' requirements.

In order to maintain the desired helium concentration and avoid room air entrainment, HELIOX21 should be administered at a flow that is sufficient to meet the patients' inspiratory flow rate and volume.

HELIOX21 should be administered at a sufficient flow in order to avoid room air entrainment and maintain the desired helium concentration.

As with all treatments for patients with airway obstruction, the patient's respiratory status should be monitored during HELIOX21 therapy, using clinical monitoring and evaluation of blood gas concentration/saturation, and adequate oxygenation must be maintained.

Method of administration Use in adults and children (all age groups).

HELIOX21 is administered by inhalation.

The duration and circumstances of the use of HELIOX21 is at the discretion of the attendant physician.

Cylinder duration is dependant on the prescribed flow rate and cylinder contents gauge should be checked to ensure there is sufficient gas available.

HELIOX21 should only be administered by trained personnel and patients should be monitored.

The physical properties of helium/oxygen mixtures are different compared to oxygen or oxygen/air mixtures, therefore be sure to use equipment designed for administration of helium oxygen mixtures in order to ensure controlled administration.

It is critical that HELIOX21 is used in combination with appropriate devices and flow rates to avoid room air entrainment and maintain the desired helium concentration.

- It can be administered by mask or when appropriate through tracheal tube or tracheostomy.
- It may also be administered via nasal prongs if sufficiently high flow rate is employed to prevent air entrainment.
- It can be administered to spontaneously breathing patients or in combination with various forms of invasive and non-invasive ventilatory modes.

HELIOX21 can be used for nebulisation therapy as the driving gas for generation of aerosol and as the carrier gas for inhalation of aerosol.

4.3 Contraindications None applicable.

4.4 Special warnings and precautions for use Medicinal gases may cause drying of mucus membranes within the respiratory tract. If use is prolonged, humidification may be required.

The risk for cooling should be taken into account, especially in smaller children. When using devices not designed for helium-oxygen mixtures, set ventilator tidal volumes and measured flow rates may not be accurate due to the physical properties of helium.

Under no circumstances should oils or grease be used to lubricate any part of the HELIOX21 cylinder or the associated equipment used to deliver the gas to the patient.

Where moisturising preparations 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.

4.5 Interaction with other medicinal products and other forms of interaction In clinical use no interactions have been reported and based on the pharmacodynamic properties no interactions are expected.

4.6 Pregnancy and lactation There is no published data that indicates that HELIOX21 adversely affects pregnancy and lactation.

Animal studies are insufficient with respect to effects on pregnancy, embryonic/ foetal development, parturition and postnatal development but in those studies published there is no evidence of harm. There is no adequate data from the use of helium/oxygen gas mixture in pregnant women.

Helium is an inert gas without pharmacological effect and it is not absorbed to any significant extent from the lung. Due to its very low solubility in blood as well as other tissues the systemic exposure is minimal. Consequently HELIOX21 does not appear to adversely affect pregnancy and lactation

4.7 Effects on ability to drive and use machines None applicable.

4.8 Undesirable effects

Very common (>1/10):	High-pitched voice.
Common (>1/100<1/10):	Drying of mucus membranes in the respiratory tract. Cooling.

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 As HELIOX21 contains 21% oxygen there is no risk of overdose.

Sufficient oxygen concentration should always be delivered to maintain adequate oxygenation of the blood.

When supplemental oxygen is administered to patients with chronic hypercapnia they should be monitored to prevent the risk of respiratory depression.

5. Pharmacological properties

5.1 Pharmacotherapeutic Group: Pharmacotherapeutic group - medical gas.

ATC code - V03AN03 helium/V03AN01 oxygen.

The helium component of HELIOX21 replaces the 79% concentration of nitrogen (N₂) present in ambient air. Helium is a noble gas with a low density, is relatively insoluble in human tissue, and has no pharmacological action in the human body. Applications of helium in respiratory care are solely related to its physical properties (low density and high capacity for diffusion of other gases) and not to any pharmacological properties. Being biologically inert, helium is non-reactive with body tissues and has no known toxic effects, even when used for extended periods of time.

There is no absolute curative effect from helium. Its ability to reduce work of breathing, shortness of breath, improvement of oxygen transport, as well as the enhancement of removal of carbon dioxide, may however have important clinical implications, supporting respiration until other drug treatments can take effect. Use of helium/oxygen mixtures can therefore prevent progression of respiratory distress and escalation of treatment.

The onset of action of HELIOX21 is rapid with improvements in pulmonary function and gas exchange observed within minutes of starting treatment.

The low density of helium allows this mixture to flow in a laminar pattern where the flow of oxygen or air would be turbulent; therefore the force necessary to move a given volume of gas is greatly reduced. Equally, for the same respiratory effort, a greater volume of gas may be inhaled.

The lower density of helium may not only affect inspiration but also facilitates expiration and thereby reduces air trapping and the risk for hyperinflation. Helium/oxygen may therefore have positive haemodynamic effects beyond the improvement in gas exchange.

Gases can diffuse more easily into helium than into nitrogen. Because of this and the improvement in gas flow helium/oxygen facilitates the removal of CO₂.

The oxygen content of the premixed helium/oxygen mixture is 21 vol.% equivalent to that of ordinary ambient air, negating the possibility of the inhalation of a hypoxic gas mixture.

5.2 Pharmacokinetic properties The absorption from the lung, and the solubility of helium in biological tissues are minimal and therefore helium has no pharmacokinetics.

Inhaled oxygen, in a concentration similar to that in ordinary ambient air is absorbed in the lung due to a pressure-dependent gas exchange between alveolar gas and the capillary blood, is transported in the blood (primarily bound to haemoglobin) and delivered to the tissues by diffusion.

5.3 Preclinical safety data There is no non-clinical safety data to indicate that helium/oxygen is harmful to humans.

6. Pharmaceutical particulars

6.1 List of excipients None.

6.2 Incompatibilities None applicable.

6.3 Shelf life 36 months.

6.4 Special precautions for storage HELIOX21 cylinders should be:

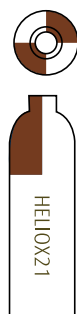
- stored vertically, under cover, preferably inside and kept dry and clean
- not stored near stocks of combustible materials
- not subjected to extremes of heat or cold
- stored separately from industrial and other non-medical cylinders
- stored to maintain separation between full and empty cylinders
- 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. Precautions should be taken to protect cylinders from theft

6.5 Nature and contents of container HELIOX21 cylinder and valve details.

A summary of HELIOX21 cylinders, their size and construction, type of valve fitted and valve outlet pressure is detailed below:

Cylinder size	Cylinder water capacity (litres)	Normal height/diameter (mm)	Normal height weight (kg)	Package materials	Gas content (litres)	Valve type filling port outlet connections outlet flowrates	Nominal valve outlet pressure bar (g)
HX	10	940/140	19.0	Steel/brass	1,750	Valve type: integral regulated Outlet (1): 6mm fir tree Flowrate: 6-15 litres/min Outlet (2): BS 5682 Shrader Flowrate: 40 litres/min (max)	4
HL	50	1,540/230	85.0	Steel/brass	8,750	Valve type: MPR non regulated Outlet (1): ISO 5145 (helium/oxygen)	200



Heliox21 cylinders are painted white (RAL 9010) with brown (RAL 8008) and white quartered shoulders. The colours conform to the requirements specified in EN 1089-3. Cylinders also carry the HELIOX21 name on the body of the cylinder.

For a limited period, cylinders may not have the name of the product on the body of the cylinder. The programme to convert all cylinders to include the name on the cylinder will be completed by 2025.

6.6 Special precautions for disposal and other handling

All personnel handling HELIOX21 medical gas 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

Cylinders fitted with integral valves (HX)

To prepare the cylinder for use:

- check the cylinder contents gauge on the cylinder valve to ensure that there is sufficient gas contents in the cylinder
- remove the tamper evident seal and cover fitted over the valve outlets
- ensure that the correct equipment is selected for connection to the cylinder.
- The tubing should be designed for use with medical oxygen and the Shrader probe should be specific to HELIOX21 use.

Connect as appropriate either:

- the appropriate sized tubing to the fir tree outlet
- the HELIOX21 Shrader probe to the Shrader outlet
- open the cylinder valve slowly and check for any leaks.

Cylinders not fitted with integral valves (HL)

- 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 the face on the equipment to be connected is clean and the sealing washer fitted is in good condition
- connect to the valve using moderate force only
- open the cylinder valve slowly and check for any leaks.

Having connected the equipment to the cylinder, check the connections for leaks using the following procedure:

- should leaks occur this will usually be evident by a hissing noise
- close cylinder valve, remove connection, check and refit
- never use excessive force when connecting equipment to cylinders
- for HL cylinders, 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 joining compounds must never be used to cure a leak

If a leak persists, label cylinder and return to BOC.

Leaks

When HELIOX21 cylinders are in use, ensure that they are:

- only used for medicinal purposes
- 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 flames.

Use of cylinders

When the HELIOX21 cylinder is empty, ensure that the:

- cylinder valve is closed, using moderate force only
- valve outlet cap, where fitted, is replaced
- empty cylinder is 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 00735/5011.

9. Date of first authorisation/renewal of the authorisation

Date first granted: 01/01/1972.
Date of renewal: not applicable.

10. Date of revision of the text

25/05/2016

11. Dosimetry (if applicable)

Not applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)

Not applicable.

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



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 HELIOX21 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.

HELIOX21 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 HELIOX21 cylinders are involved in a fire:

- if it is safe to move the cylinders,
 - close cylinder valve to stop the 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 HELIOX21 cylinders. No special protective equipment for fire fighters is required. There are no hazardous combustion products released from the gas.

4. Accidental release measures If a large volume of HELIOX21 is released, if it is safe to do so, you should:

- close cylinder valve
- where possible, eliminate all sources of ignition.

If the 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 HELIOX21 is released in a confined area.

5. Exposure controls When using HELIOX21 cylinders, ensure adequate ventilation.

6. Disposal considerations It is recommended that HELIOX21 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 HELIOX21 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. Transport information

UN number	UN1956
Proper shipping name:	Compressed gas NOS
Material:	Class 2
Labels	2.2
Hazard identification number	20
Emergency Action Code	2TE
Tunnel Restriction Code	E
Transport category	3

Notes.

Notes.

BOC Healthcare

Customer Service Centre, Priestley Road, Worsley, Manchester M28 2UT

Tel 0800 111 333, Fax 0800 111 555, bohealthcare-uk@boc.com, www.bohealthcare.co.uk

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