

**Heliox28**  
**AUST R 90662**

**PRODUCT INFORMATION**

**11 August 2003**

## Heliox28

### NAME OF THE DRUG

Heliox28 - Oxygen 28% v/v and Helium 72% v/v

### Chemical structure

Oxygen has a molecular structure of O=O

Helium symbol is He

### CAS Number

Oxygen – 7782-44-7

Helium – 7440-59-7

### DESCRIPTION

#### Pharmaceutical form

Compressed medical gas mixture (for medicinal use only).

Heliox28 is a homogenous gas mixture of oxygen 28% v/v and helium 72% v/v.

Oxygen is the active ingredient.

#### Specification

The specifications for each of the main components are presented separately.

##### Oxygen

Complies with the requirements of the current European Pharmacopoeia monograph for Oxygen.

Oxygen	99.5% v/v minimum
Carbon dioxide	300 ppm v/v maximum
Carbon monoxide	5 ppm v/v maximum
Water (vapour)	67 ppm v/v maximum

##### Helium

Complies with BOC specification for Medical Helium.

Helium	99.99% v/v minimum
Hydrocarbones as Methane	1 ppm v/v maximum
Carbon monoxide	5 ppm v/v maximum
Water (vapour)	67 ppm v/v maximum

#### Physical data

Molecular/ Atomic weight	O <sub>2</sub> 32.00, He 4.0026
Physical state in the cylinder	High pressure gas at ambient temperature
Combustion characteristics	Non flammable but strongly supports combustion

Oxygen is a colourless, odourless and tasteless gas. Helium is a colourless, odourless, non-flammable gas.

#### Chemical characteristics

Oxygen is an oxidising substance which will support combustion of materials which may not normally burn in air. Helium is an inert gas with low chemical activity. Helium is less dense than any other known gas except hydrogen and is about one seventh as dense as air.

### PHARMACOLOGY

Oxygen is a naturally occurring element which is essential for metabolism and homeostasis in man. It comprises approximately 21% of atmospheric air.

Helium is a biologically inert element which is approximately seven times less dense than nitrogen.

The oxygen/helium mixture therefore has a lower density than air and, in the presence of airway obstruction, is more likely to be associated with laminar, rather than turbulent, flow. This results in improved oxygen delivery to the alveoli.

#### Pharmacokinetics

Oxygen is absorbed into the systemic circulation and distributed throughout the body.

Helium has low solubility in human tissues at atmospheric pressure and is therefore not significantly absorbed systemically.

### CLINICAL TRIALS

Multiple clinical trials of oxygen/helium mixtures in the management of conditions associated with airway obstruction have been reported in the published literature. These studies have been predominantly conducted in patients with chronic obstructive pulmonary disease (COPD) or asthma

In controlled trials in these conditions, the use of helium/ oxygen has been associated with improvements in peak expiratory flow rate (PEFR), reductions in PaCO<sub>2</sub> and work of breathing, reversal of acidosis and decreased dyspnoea.

### INDICATIONS

Heliox28 is indicated in treatment of hypoxia associated with airway obstruction.

### CONTRAINDICATIONS

Heliox28 should not be used where its high diffusivity might exacerbate conditions, such as with artificial, traumatic or spontaneous pneumothorax or sub-cutaneous emphysema.

### PRECAUTIONS

#### General

Oxygen saturation levels should be monitored in patients receiving Heliox28. If oxygen saturation is not adequately maintained, additional oxygen may be mixed with Heliox28. However caution should be exercised to avoid oxygen toxicity (eg retinopathy in premature neonates treated with prolonged hyperoxygenation).

Caution should also be exercised in patients with chronic obstructive pulmonary disease (COPD), in whom respiration may be dependant upon hypoxic drive. In hypercarbic COPD patients, arterial blood gases should be monitored to detect any increase in acidosis.

Smoking is prohibited when the product is in use and no naked flames should be allowed.

#### Check the following before use

Cylinders should be stored upright below 45°C in a dry well ventilated area.

Heliox28 is non-flammable but strongly supports combustion (including some materials which do not normally burn in air). It is highly dangerous when Heliox28 comes into contact with oils, greases and tarry substances due to the risk of spontaneous combustion.

Dispensing equipment connection matches cylinder valve pin index outlet and demand valve is operational.

Cylinder pressure may be used as an indicator of the quantity of the gas remaining in the cylinder.

#### Use of gas cylinders

Cylinders should be kept out of the reach of children.

Care is needed in the handling and use of Heliox28 gas cylinders. Heliox28 is stored in high pressure gas cylinders under pressure at ambient temperature.

Additional information is contained in the Material Safety Data Sheet for Heliox28 from the sponsor.

#### Carcinogenicity and mutagenicity

Long-term animal studies on carcinogenicity are not available for helium/ oxygen gas mixtures.

A 50 or 100 atmosphere helium/0.21 atmosphere oxygen gas mixture was not mutagenic in TA98 and TA100 strains of *Salmonella typhimurium*.

#### Impairment of fertility

There are no adequate human or animal studies addressing the effect of helium/ oxygen gas mixtures on fertility or reproductive performance.

**Use in pregnancy**

No relevant epidemiological data or adequate and well-controlled clinical data on exposed pregnancies are available for helium/ oxygen gas mixtures.

No data from animal studies using mammalian species that would enable assignment of a 'Use in Pregnancy' classification are available.

Studies in chicken eggs exposed continuously to a 21% oxygen/79% helium gas environment from lay up to 4 weeks post-hatch have revealed impaired hatchability, increased embryonic mortality and decreased embryonic weight.

Use of Heliox28 is not recommended during pregnancy, unless clearly necessary.

**Use in lactation**

There are no adequate human or animal studies addressing the effect of helium/ oxygen gas mixtures on lactation.

**Effects on the ability to drive and to use machines**

There is no evidence on the effects of Heliox28 on the ability to drive and use machinery.

**Interactions with other drugs**

There are no adequate human or animal studies reports on interaction of helium/ oxygen mixtures with other drugs available.

**Effects on Laboratory Tests**

There are no known significant effects on laboratory tests after exposure to Heliox28.

**ADVERSE REACTIONS**

Increased vocal pitch and voice distortion due to helium.

Inhalation of Heliox28 has the potential to cause drying of mucous membranes, including the drying out of bronchial secretions and subsequent atelectasis.

Prolonged inhalation of helium has the potential to cause a reduction in body temperature.

The use of helium/oxygen has been observed to cause hypoxia in neonates with bronchopulmonary dysplasia and subglottic stenosis.

**DOSAGE AND ADMINISTRATION****Routes of administration**

Heliox28 is administered by inhalation through the lungs. Heliox28 should only be administered by medical personnel trained in the appropriate techniques and in an adequate environment.

The method of administration is to supply the medical gas mixture directly from the outlet of the medical cylinder valve, via an appropriate flexible hose connected to either a face mask or cannula, a demand valve with face mask or cannula attached, a nebuliser or inhaler with face mask attached or a ventilator.

Cylinders should only be used in conjunction with special Heliox28 gas pressure regulators and demand valves.

Safety of long term administration of Heliox28 has not been studied.

**OVERDOSAGE**

None applicable.

**PRESENTATION**

Please consult the Material Safety Data Sheet for helium/ oxygen gas mixture from the sponsor.

**Pharmaceutical form**

Compressed medical gas (for medicinal use only) supplied in cylinders in accordance with AS2030 and pin index valve in accordance with AS2472.

Cylinder colour:                      Shoulder: brown and white quadrants

Body: neutral with white plastic sleeve with Heliox28 and Helium/Oxygen artwork.

Cylinder valve outlet: Regulated to 400 kPa, either AS2896 sleeve outlet (300 lpm) or barbed tail (0 to 15 lpm)

Cylinder size (nominal water capacity, liters): CD (2.4L); ED (23.8L)

Cylinder size (gas volume, liters – @ 15°C; 1 At): CD (510L); ED (3500L)

### Storage

The normal precautions required in the storage and use of medical gas cylinders are applicable. Please refer to Commonwealth, State and Territory Dangerous Goods legislation and the appropriate Australian Standards i.e. AS 4332. Cylinders should be stored away from sources of ignition, poisons, flammable or combustible materials. They should preferably be stored upright, in a secure area, below 45°C, in a dry well ventilated area constructed of non-combustible material with a firm, level floor (preferably concrete) away from heavy traffic and emergency exits.

### NAME AND ADDRESS OF THE SPONSOR

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