Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Medical Liquid Oxygen 100% Medicinal gas, cryogenic

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxygen Ph. Eur. 100%.

There are no other ingredients.

3 PHARMACEUTICAL FORM

Medicinal gas, cryogenic.

Light blue cryogenic liquid of about - 180 °C contained within a closed container/vessel (see section 6.5). The liquid rapidly evaporates to form oxygen gas.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- At high concentrations in the treatment of acute severe asthma, pulmonary thrombo-embolism, pneumonia and fibrosing alveolitis.
- At low concentrations in the treatment of ventilatory failure due to chronic obstructive airways disease and other causes.
- For the treatment of carbon monoxide poisoning.
- To reduce the volume of air trapped in body cavities, as for example, in patients with pneumothorax, air embolism and decompression sickness. Inhalation of air containing a high concentration of oxygen (and hence low concentration of nitrogen) enhances removal of trapped oxygen.
- Pulmonary oedema.
- As a diluent or carrier gas in anaesthesia.
- Other indications include cystic fibrosis, shock, severe anaemia, sleep apnoea, cluster headaches and anaerobic infections.

4.2 Posology and method of administration

High concentration oxygen therapy, with concentrations up to 60% for short periods is safe for conditions like acute severe asthma, pulmonary thrombo-embolism, pneumonia and fibrosing alveolitis. Low concentration (controlled) oxygen therapy should be used in patients with ventilatory failure due to chronic obstructive airways disease and other causes. The concentration should not exceed 28%.

Oxygen may be administered at concentrations of up to and including 100% although with most delivery systems inspired concentrations over 60% (80% in children) are unlikely to be achieved. In practice 24% is usually taken as the lower limit, with allowance for a safety margin. The dosage is adapted to the patient on the basis of the clinical course of the illness and generally ranges from 1 to 10 litres of gas per minute.

Systems for longer-term oxygen therapy usually rely on a mixture of air and additional oxygen being supplied. Masks, nasal cannulae, etc. can provide fixed or variable mixtures depending on their design. In circumstances where oxygen is not being mixed with air, but is mixed with other gases (e.g. anaesthetics and analgesics) then it is essential that the proportion of oxygen in the inspired mixture never falls below the concentration in air. In practice 30% is usually taken as a lower limit, with allowance for a safety margin.

Care should be taken to prevent rebreathing of expired carbon dioxide. With vented face masks and flow rates over 4 litres/minute this should rarely be a problem.

In an emergency a doctor may need to administer doses considerably higher to patients with severe breathing difficulties. Such doses may be up to 60 litres per minute, controlled by special flowmeters.

Other systems of administration include face tents, headboxes, cot hoods and supply to a tracheostomy.

In severe hypoxia the use of a positive pressure mask may be valuable. This technique should only be used by experienced practitioners.

4.3 Contraindications

Normobaric oxygen therapy:
None

Hyperbaric oxygen therapy (HBOT):
Undrained/untreated pneumothorax (see section 4.4).

4.4 Special warnings and precautions for use

High oxygen concentrations should be given for the shortest possible time required to achieve the desired result, and must be monitored with repeated checks of arterial gas pressure (PaO2) or haemoglobin oxygen peripheral saturation (SpO2) and clinical assessment.

Patients at risk of hypercapnic respiratory failure

Special caution should be applied in patients with reduced sensitivity to the carbon dioxide tension in arterial blood or at risk of hypercapnic respiratory failure ("hypoxic drive") (e.g. patients with chronic obstructive pulmonary disease (COPD), cystic fibrosis, morbid obesity, chest wall deformities, neuromuscular disorders, overdose of respiratory depressant drugs). The administration of supplemental oxygen may cause respiratory depression and a rise in PaCO2 with subsequent symptomatic respiratory acidosis (see section 4.8). In these patients, oxygen therapy should be carefully titrated; the target oxygen saturation to be achieved may be lower than in other patients and oxygen should be administered at a low flow rate.

Special caution in patients with bleomycin lung injury

The pulmonary toxicity of high-dose oxygen therapy can potentiate lung injury, even if given several years after the initial lung injury by bleomycin and the target oxygen saturation to be achieved may be lower than in other patients (see section 4.5).

Paediatric population

Because of the higher sensitivity of newly born to supplemental oxygen, the lowest effective concentrations should be sought in order to achieve an adequate oxygenation appropriate for neonates.

In preterm and newborn infants, increased PaO2 may lead to retinopathy of prematurity (see section 4.8). It is recommended to start resuscitation of term or near term neonates with air instead of 100% oxygen. In preterm, the optimal concentration of oxygen and oxygen target are not precisely known. Supplemental oxygen, if required, will then be closely monitored and guided by pulse oximetry.

Hyperbaric oxygen therapy (HBOT)

Hyperbaric oxygen therapy should only be administered by qualified staff and in specialized centers aware and equipped for ensuring appropriate precautions for hyperbaric use. The pressure should be increased and reduced slowly in order to avoid the risk of pressure damage (barotrauma).

Confinement anxiety and claustrophobia can occur during the HBOT session in the chamber. The benefit/risk ratio of HBOT should be thoroughly evaluated in patients with claustrophobia, severe anxiety, psychosis.

Respiratory disorders

Because of the decompression, at the end of the hyperbaric session, the gas volume increases while the pressure in the chamber decreases, which may lead to partial pneumothorax or aggravation of an underlying pneumothorax. In a patient with

an undrained pneumothorax, decompression could lead to the development of a tension pneumothorax. In cases of pneumothorax, pleural cavities must be drained before the session and it may be required to continue the drainage procedure during the HBOT session (see section 4.3). Moreover, considering the risk of gas expansion during the decompression phase of HBOT, the benefit/risk ratio of HBOT should be thoroughly evaluated in patients with insufficiently controlled asthma, pulmonary emphysema, chronic obstructive pulmonary disease (COPD), and recent thoracic surgery.

Diabetic patients

Blood glucose decrease during HBOT session has been reported. Hence, it may be preferable to monitor blood glucose before HBOT session in diabetic patients.

Coronary diseases

The benefit/risk ratio of HBOT should be thoroughly evaluated in patients with coronary diseases. In patients with acute coronary syndrome or acute myocardial infarction who also require HBOT, such as in case of CO intoxication, HBOT should be used cautiously because of the vasoconstriction potential of hyperoxia in the coronary circulation.
Ear, nose and throat disorders: In relation to the compression/decompression of HBOT, caution and thorough assessment of the benefit/risk ratio of HBOT are required in patients with sinusitis, otitis, chronic rhinitis, laryngocele, mastoid cavity, vestibular syndrome, hearing loss and recent middle ear surgery.

Relating to hyperoxia induced by HBOT, the benefit/risk ratio of HBOT should be thoroughly evaluated in patients with:
- History of seizure, epilepsy
- Uncontrolled high fever

Risk of fire

Oxygen is an oxidizing product and promotes combustion. Whenever oxygen is used, the increased risk of fire ignition should be taken into account:
- Risk of fire in domestic environment: Patients and caregivers should also be warned about the risk of fire in presence of other sources of ignition (smoking, flames, sparkles, cooking, ovens etc.) and/or highly combustible substances, especially greasy substances (oils, grease, creams, ointments, lubricants etc.). Only water-based products should be used on the hands and face or inside the nose while using oxygen.
- Risk of fire in the medical environment: this risk is increased in procedures involving diathermy, defibrillation and electro conversion therapy.
- Fires can occur at valve opening (frictional heating).

Thermal burns have occurred related to accidental fires in presence of oxygen.

Handling of the cylinders

Caretakers and all people who handle medicinal oxygen cylinders should be warned about the need to carefully handle cylinders to prevent damages to the equipment, especially the valve. Equipment damage may cause obstruction of the outlet and/or wrong information displayed on the manometer with regards to remaining oxygen content and flow delivery leading to insufficient or lack of oxygen administration.

4.5 Interaction with other medicinal products and other forms of interaction

Inhalation of high concentration of oxygen can exacerbate the pulmonary toxicity associated with drugs such as bleomycin (even if oxygen is given several years after the initial bleomycin-induced lung injury), amiodarone, nitrofurantoin and with paraquat intoxication. Unless the patient is hypoxemic, supplemental oxygen should be avoided.

In the presence of oxygen, nitric oxide is rapidly oxidized to form superior nitrated derivatives that are irritant for the bronchial epithelium and the alveolocapillary membrane. Nitrogen dioxide (NO_2) is the principal compound formed. The oxidation rate is proportional to the initial concentrations of nitric oxide and oxygen in the inhaled air, and to the duration of contact between NO and O_2.

There is a risk of fire in the presence of other sources of ignition (smoking, flames, sparkles, ovens etc.) and/or highly combustible substances (oils, grease, creams, ointments, lubricants etc.) (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

In animal tests, toxicity to reproduction was observed after administration of oxygen at increased pressure or in high concentration. It is unknown to what extent these findings are relevant to humans.

Normobaric oxygen therapy:
Oxygen can be used during pregnancy only when necessary i.e. in case of vital indications, women either critically ill or with hypoxemia.

Hyperbaric oxygen therapy (HBOT):
The amount of documented experience with the use of HBOT in pregnant women is limited, but has shown a benefit of HBOT for the foetus in case of CO intoxication in pregnant women. In other situations, HBOT should be used with caution in pregnancy as the impact on the foetus of a potential increase of oxidative stress from excess oxygen is unknown. The use of HBOT should then be evaluated in each individual patient but is permissible in the case of vital indications during pregnancy.

Lactation

Oxygen therapy can be used during breastfeeding without risk to the infant.

4.7 Effects on ability to drive and use machines

Normobaric oxygen therapy:
Oxygen has no influence on the ability to drive and use machines.

Hyperbaric oxygen therapy (HBOT):
Vision and hearing disorders which may affect the ability to drive and use machines have been reported after HBOT (see section 4.8).

4.8 Undesirable effects

Description of selected adverse events

Respiratory adverse events
- At an ambient pressure, the first signs (tracheobronchitis, substernal pain and dry cough) appear as soon as after 4 hours of exposure to 95% oxygen. A reduced forced vital capacity can occur within 8-12h of exposure to 100% oxygen, but serious injuries require much longer exposures. Interstitial oedema can be seen after 18h of exposure to 100% oxygen and can lead to pulmonary fibrosis. Respiratory effects reported with HBOT are generally similar to those encountered during normobaric oxygen treatment, but the time to symptom onset is shorter.

- With high concentrations of oxygen in the inspiratory air/gas, the concentration/pressure of nitrogen is reduced. As a result, the concentration of nitrogen in tissues and lungs (the alveoli) falls. If oxygen is taken up from the alveoli into the blood more rapidly than it is supplied in the inspiratory gas fraction, alveolar collapse can occur (development of atelectasis). The development of atelectatic sections of the lungs leads to a risk of poorer arterial blood oxygen saturation, despite good perfusion, due to lack of gas exchange in the atelectatic sections of the lungs. The ventilation/perfusion ratio worsens, leading to intrapulmonary shunt.

- There may be a change in the modalities of ventilation control in patients with long-term diseases associated with chronic hypoxia and hypercapnia. Under these circumstances, administration of too high concentrations of oxygen can cause respiratory depression, inducing aggravated hypercapnia, respiratory acidosis, and finally respiratory arrest (see section 4.4).

Central nervous toxicity

Central nervous toxicity can be observed in HBOT settings. Central nervous toxicity can develop when patients breathe 100% oxygen at pressures above 2 ATA. Early manifestations include blurred vision, peripheral vision decreased, tinnitus, respiratory disturbances, localized muscular twitching especially eyes, mouth, forehead. Continuation of exposure can lead to vertigo and nausea followed by altered behaviour (anxiety, confusion, irritability), and finally generalized convulsions. The

hyperoxia-induced discharges are believed to be reversible, causing no residual neurological damage, and disappearing upon reduction of the inspired oxygen partial pressure.

Eye toxicity

Progressive myopia has been reported in cases of multiple hyperbaric treatments. The mechanism remains obscure but an increase refractory index of the lens was suggested. Most cases were spontaneously reversible. However, risk of irreversibility increased after more than 100 therapies. After stopping HBOT, reversal of myopia was usually rapid for the first few weeks and then continued more slowly for periods ranging from several weeks to as long as a year. The threshold of number of HBOT sessions, periods or duration cannot be estimated. It was ranged from 8 to more than 150 sessions. – Retinopathy of prematurity: see below.

Pediatric population

In premature neonates who have been subjected to high oxygen concentrations, retinopathy of prematurity (retrolental fibroplasia) may occur.

Risk of fire

The risk of fire is increased in presence of high concentrations of oxygen and sources of ignition potentially leading to thermal burns (see section 4.4)

Adverse events related to HBOT procedure

- Undesirable effects of HBOT are barotraumas or consequences of multiple and rapid compressions/decompressions. Most of them are not specific to the use of oxygen and can occur in patients under oxygen as well as in attending healthcare professionals under hyperbaric ambient air. These are ear, sinuses and throat barotraumas, pulmonary barotraumas, other barotraumas (teeth, etc.).

- Due to the relatively small size of some hyperbaric chambers, patients may develop claustrophobia that is not due to a direct effect of oxygen.

Adverse reactions associated with Oxygen Therapy

System organ class	**Very common (> 1/10)**	**Common (≥ 1/100 to < 1/10)**	**Uncommon (≥ 1/1000 to < 1/100)**	**Rare (≥ 1/10,000 to < 1/1,000)**	**Very rare (< 1/10,000)**	**Undetermined frequency**
Respiratory, thoracic and mediastinal disorders			Atelectasis			Pulmonary toxicity: • Tracheobronchitis (substernal pain, dry cough) • Pulmonary fibrosis Worsening of hypercapnia in patients with chronic hypoxia/hypercapnia treated with too much elevated FiO2: • Hypoventilation • Respiratory acidosis • Respiratory arrest

Eye disorders	Retinopathy of prematurity					
General disorders and administration site conditions						Mucosal dryness Local irritation and inflammation of the mucosa

Adverse reactions specific to Hyperbaric Oxygen Therapy

System organ class	**Very common (> 1/10)**	**Common (≥ 1/100 to < 1/10)**	**Uncommon (≥ 1/1000 to < 1/100)**	**Rare (≥ 1/10,000 to < 1/1,000)**	**Very rare (< 1/10,000)**	**Undetermined frequency**
Respiratory, thoracic and mediastinal disorders				Dyspnoea		Respiratory disturbances
Nervous system disorders		Seizure				
Musculoskeletal and connective tissue disorders						Localized muscular twitching
Ear and labyrinth disorders	Ear pain		Tympanic membrane rupture			Vertigo Hearing impaired Acute serous otitis media Tinnitus
Gastrointestinal disorders						Nausea
Psychiatric disorders						Abnormal behaviour Claustrophobia
Eye disorders	Progressive myopia					Peripheral vision decreased Blurred vision Cataract*
Injury, poisoning and procedural complications	Barotrauma (sinuses, ear, lung, teeth etc.)					
Metabolism and nutrition disorders				Hypoglycemia in diabetic patients		

* The development of cataracts has been reported in patients undergoing prolonged courses and/or frequently repeated sessions of HBOT (> 150 sessions). Some cases of de novo/new cataract have been observed.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

The toxic effects of oxygen vary according to the pressure of the inhaled oxygen and the duration of exposure.

Symptoms of oxygen intoxication are those of hyperoxia.

The symptoms of respiratory toxicity include from tracheobronchitis (substernal pain, dry cough) to interstitial oedema and pulmonary fibrosis.

The symptoms of central nervous toxicity that are observed in HBOT settings, include tinnitus, respiratory disturbances, localized muscular twitching especially eyes, mouth, forehead. Continuation of exposure can lead to vertigo and nausea followed by altered behaviour (anxiety, confusion, irritability), and finally generalized convulsions.

Eye toxicity includes blurred vision and reduced peripheral vision within HBOT settings.

Paediatric population
Eye toxicity in neonates: in premature neonates who have been subjected to high oxygen concentrations, retinopathy of prematurity may occur.

Patients at risk of hypercapnic respiratory failure
The administration of supplemental oxygen may cause respiratory depression and a rise in $PaCO_2$ with subsequent symptomatic respiratory acidosis

In case of oxygen intoxication related to hyperoxia, oxygen therapy should be reduced or if possible stopped, and symptomatic treatment should be started

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

All other therapeutic products, Medical Gases, ATC class: VO3AN01

The characteristics of oxygen are:
Odourless, colourless gas.
Molecular weight 32.00
Boiling point -183.1 degrees Celsius (at 1 bar)
Density 1.355kg/m3 (at 15° Celsius)

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

The basal oxygen consumption in man is about 250ml/min for a body surface of 1.8sq metres. It is reduced by about 10% during anaesthesia and natural sleep and by about 50% for a 10 degree Celsius fall in body temperature.

Alveolar air contains about 15% oxygen at 14 kpa (105mm Hg) and arterial blood has an oxygen tension of 13 kpa (97mm Hg).

The difference, known as the alveolar-arterial oxygen tension gradient, increases with age. The difference may be as great as 4kpa (30mm Hg) in a healthy, elderly individual.

Oxygen in the blood is mostly combined with haemoglobin. Normally, haemoglobin in arterial blood is 97% saturated and the oxygen content of the blood is 19.8 vol%, 0.3ml of this being carried in solution. The remainder is held in chemical combination with haemoglobin.

The concept of oxygen availability can be expressed as the product of the cardiac output and the oxygen content of the blood.

The average healthy individual with a basal oxygen consumption has no more than 4 minutes supply of oxygen in the blood.

5.2 Pharmacokinetic properties

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 5kpa (40mm Hg) and 2kpa (15mm Hg) the oxygen carried in the blood from the lungs can readily be given up to the tissues.

The uptake from the lungs is rapid because blood flow through the capillaries, where the 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.

At rest, mixed venous blood returning to the lungs contains 13-14ml of oxygen per 100ml, but with severe exercise, the oxygen content may fall to 3-4ml. In very active tissue, almost complete extraction occurs.

5.3 Preclinical safety data

Experience of oxygen therapy has largely derived from experience in man. Thus, whilst there obviously have been laboratory studies, there are no formal 'pre-clinical' observations to report.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

6 months

6.4 Special precautions for storage

Liquid oxygen containers should be kept out of the reach and sight of children.
Oxygen is non flammable but strongly supports combustion. It is highly dangerous when in contact with oils and greases due to the risk of fire.
The normal precautions required in the storage of medical gas containers as described below are applicable:

- Containers should be stored separately from containers containing non-medical gases
- Medical containers containing different medical gases should be segregated and identified.
- Full and empty containers should be stored separately.
- Containers should be stored vertically.
- Containers should be stored under cover, kept dry and clean and not subjected to extremes of temperature.
- Containers should not be stored near stocks of combustible materials or sources of heat.
- Warning notices prohibiting smoking and naked lights should be clearly posted.
- Emergency services should be advised of the location of the Medical Liquid Oxygen store.
- Precautions should be taken to protect containers from theft.

6.5 Nature and contents of container

The medical liquid oxygen is packaged in vacuum insulated containers made of stainless steel specifically designed to store cryogenic gases at low temperatures (about -180 °C). The transportable medical liquid oxygen supply vessel – 10 litre, 20 litre, 21 litre, 30 litre, 31 litre, 32 litre, 36 litre, 37 litre, 41 litre, 42 litre, 45 litre, 46 litre and 60 litre is supplied for use at the customer's location.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Use in accordance with the doctor's instruction.

GENERAL

- Pipelines for medical gases should be controlled in accordance with the conditions set out in HTM 02.
- All personnel handling gas cylinders or being responsible for pipeline gas supplies should have adequate knowledge of:

- the properties of the gas,
- precautions to be taken,
- actions in the event of any emergency
- the correct operating procedures for their installation.

- If you own your own cylinders, you must be aware of and discharge your statutory obligations with regard to maintenance and testing.
- Ensure that when cylinders are collected the driver has been properly instructed in the method of handling cylinders and in dealing with any emergency.

PREPARATION FOR USE

- To prepare the cylinder for use, before placing near the patient
- Ensure that the correct cylinder has been selected – check that the cylinder contains Medical Oxygen (Read the label on the cylinder).
- Ensure that the gas is within its expiry date (this is specified on a separate batch label on the shoulder of the cylinder).
- Remove the tamper evident seal (this is only applicable for the first use of the cylinder).
- Ensure that the cylinder is turned off.

Cylinders used with a separate pressure regulator

- Check the gas pressure in the cylinder (read the label) and ensure that the cylinder is compatible with the equipment that it is being connected to. Only the appropriate regulator should be used for the particular gas concerned, correct for the specific product type and the cylinder pressure.
- Ensure that the connecting face of the pin-index valve, the manifold connection or the bullnose outlet of the valve and the regulator connection is clean and free from damage.
- Inspect any seal fitted to the regulator connector for signs of wear or feathering of the seal material or contamination with oil or grease. Replace the seal if there are any signs of wear, damage or contamination.
- Never use oil or grease or any lubricant to connect equipment to a cylinder valve.
- Connect the regulator. Tighten by hand using moderate force to make the connection. Do not use excessive force.
- Ensure that any equipment connected to the cylinder is turned off and any flow device fitted to the regulator is set to zero.
- Connect the appropriate size tubing to the tubing nipple outlet or the medical oxygen probe to the quick connect outlet (where fitted)
- Select the required flowrate (if appropriate)Turn the cylinder on slowly by opening the cylinder valve
- Check the connection for leaks.

- Should leaks occur, this would usually be evident by a hissing noise.
- If the leak occurs between the valve outlet and the regulator or the manifold connector, turn off the cylinder, depressurise and remove the connector. Replace the seal and reconnect the equipment following the instructions above.
- Sealing or joining compounds must never be used to cure a leak.
- Never use excessive force when connecting equipment to cylinders.
- If the leak persists, label the cylinder and arrange return of the cylinder to your supplier.

Cylinders with an integral pressure regulator valve

- Ensure that the correct equipment is selected for connection to the cylinder valve.
- Never use oil or grease or any lubricant to connect equipment to a cylinder.
- Ensure the flow control (if fitted) is set to zero.
- Connect the appropriate sized tubing to the tubing nipple or the medical oxygen probe to the quick connect outlet on the cylinder (where fitted).
- Turn the cylinder on slowly, open the cylinder valve.
- Check the connection for leaks Should leaks occur, this would usually be evident by a hissing noise.

- If a leak is found, close the valve remove the connection, check and refit.
- Never use excessive force when connecting equipment to cylinders.
- If the leak persists, label the cylinder and arrange return of the cylinder to your supplier.

USE OF CYLINDERS

- Medical gases must only be used for medicinal purposes.

- When cylinders are not in use they should be turned off, use moderate force to close the valve.
- Smoking and naked lights must not be allowed within the vicinity of cylinders or pipeline outlets.
- Cylinders should be handled with care, never knocked violently or allowed to fall over. Dropping a cylinder can damage the valve and may cause injury. If the cylinder is dropped or knocked in use it must be checked before further use.
- Never roll cylinders along the ground. Cylinders should only be moved with the appropriate size and type of trolley or using the correct handling techniques. Ensure that the cylinder is securely stowed when moving the cylinder.
- When in use, cylinders should be firmly secured to a suitable cylinder support. Take care as lightweight cylinders can be damaged by sharp objects such as securing screws.
- Do not place the cylinder on the patient's bed unless there is no suitable alternative for retaining the cylinder.
- Cylinders must not be repainted or have any marking obscured or labels removed.

AFTER USE

- Turn off the supply of Medical Oxygen by closing the cylinder valve using moderate force only.
- Allow the equipment to vent any residual gas.
- If fitted turn the flow control to zero.
- Disconnect the equipment used to deliver the gas to the patient. Return empty cylinders to the empty cylinder store.
- Contact your supplier to arrange refill of the cylinder by Industrial Pressure Testing Ltd Unit H5 Marina Commercial Park Cork, Ireland.
- Cylinders that are no longer required should be returned to your supplier.

7 MARKETING AUTHORISATION HOLDER

Air Liquide Healthcare Ireland Limited
25/28 North Wall Quay
North Wall
Dublin 1
Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER

PA22852/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 31st May 2024

10 DATE OF REVISION OF THE TEXT