SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Medicinal Oxygen Air Liquide 100%, Medicinal gas, compressed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxygen 100% at a pressure of 200 bar (15°C).

3. PHARMACEUTICAL FORM

Medicinal gas, compressed
Colourless, odourless and tasteless

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Oxygen therapy
- For treatment or prevention of acute and chronic hypoxia irrespective of cause.
- As part of the fresh gas flow in anaesthesia or intensive care.
- As the propellant in nebuliser treatment.
- For treatment of an acute attack of cluster headache

Hyperbaric oxygen therapy
For treatment of decompression sickness, air/gas emboli from other causes and carbon monoxide poisoning. Treatment of patients who have been exposed to carbon monoxide is especially indicated in pregnant patients or patients who are or have been unconscious, or who have displayed neurological symptoms and/or cardiovascular effects or severe acidosis, irrespective of the measured COHb value.

As adjunct treatment in:
- severe osteoradionecrosis, clostridium myonecrosis (gas gangrene).

4.2 Posology and method of administration

Posology
Oxygen therapy

The aim of treatment is to ensure, by adjusting the oxygen fraction in the inhaled air (FiO_2), that the oxygen partial pressure in arterial blood (PaO_2) does not fall below 8.0 kPa (60 mmHg) or that the oxygen saturation of haemoglobin in arterial blood does not fall below 90%.

The dose (FiO_2) must be adjusted according to each patient's individual needs, taking into account the risk of oxygen toxicity. A general recommendation is to use the lowest dose (FiO_2) necessary to achieve the desired result of treatment. In cases of pronounced hypoxia, oxygen fractions that can involve a risk of oxygen toxicity may be indicated. (See section 4.9).

The treatment must be continuously evaluated and the effect measured by means of PaO_2 or arterial oxygen saturation (SpO_2).

In short-term treatment with oxygen, the oxygen concentration - the fraction in the inhaled gas mixture (FiO_2) (avoid >0.6 = 60% O_2 in the inhaled gas mixture) - must be kept so that, with or without positive end-expiratory pressure (PEEP) or continuous positive airway pressure (CPAP), an arterial oxygen pressure (PaO_2) > 8 kPa can be achieved.

Short-term treatment with oxygen must be monitored/followed with the aid of repeated measurements of arterial oxygen pressure (PaO_2) or pulse oximetry, which gives a numerical value for haemoglobin oxygen saturation (SpO_2). However, these are only indirect measurements of the oxygen saturation in tissues. The effect of the treatment should also be evaluated clinically.

In the emergency/acute setting the usual dose for adults to treat or prevent *acute oxygen deficiency* is 3-4 litres per minute when using nasal prongs, or 5-15 litres per minute with a mask.

In long-term treatment, the need for extra oxygen is guided by the result of arterial blood gas measurements. For adjusting oxygen therapy in patients with hypercapnia, blood gases must be monitored in order to avoid a marked increase in arterial carbon dioxide tension.

If the oxygen is mixed with other gases, the concentration of oxygen in the inhaled gas mixture (FiO_2) must not be lower than 21% and may be up to 100%.

For treatment of cluster headache, oxygen is to be delivered by a facemask, in a non re-breathing system. Oxygen therapy should be instituted early after onset of the attack and should last for about 15 minutes or until the pain has disappeared. Usually a flow of 7 to 10 l/min is sufficient but a flow up to 15 l/min might be necessary to some patients to reach efficacy. Oxygen should be discontinued if no effect occurs after 15 to 20 minutes.

Hyperbaric oxygen therapy
Hyperbaric oxygen therapy (HBO) involves administering 100% oxygen at a pressure exceeding 1.4 times the atmospheric pressure at sea level (1 atmosphere = 101.3 kPa = 760 mmHg). For safety reasons the pressure in HBO should not exceed 3 atmospheres. The duration of one treatment session with HBO at a pressure corresponding to 2 to 3 atm is normally between 60 minutes and 4–6 hours, depending on the indication. Treatments may be repeated 2–3 times daily if necessary, depending on the indication and the clinical condition. Repeated treatments are most often necessary for the treatment of soft tissue infections and ischaemic ulcers that do not respond to conventional therapy. HBO must be given by personnel who are competent to do so. Increasing and reducing the pressure must be done slowly in order to avoid the risk of pressure damage (barotrauma).

Paediatric population
In neonates, careful monitoring should be performed during the treatment. The lowest effective concentrations should be sought in order to achieve an adequate oxygenation.

Method of administration
Oxygen therapy:
Oxygen is administered via the inspiratory air.

Oxygen can also be supplied through a so-called ‘oxygenator’ directly to the blood in cases of, among other things, cardiac surgery with a heart–lung machine, and in other conditions that require extracorporeal circulation.

Oxygen is administered by means of equipment intended for this purpose. With this equipment, the oxygen is supplied to the inspiratory air, and, on expiration, the exhaled gas with any excess of oxygen, passes from the

patient and is mixed with the surrounding air (non-rebreathing system). For treatment of cluster headache, oxygen is to be delivered by a facemask, in a non re-breathing system.
For anaesthesia, special equipment is often used in which the exhaled gas recirculates and can, in part, be re-inhaled (circular system with rebreathing).
There are a large number of devices intended for oxygen administration.

Low-flow system:
The simplest system, which mixes oxygen with the inhaled air, e.g. a system in which the oxygen is dosed via a simple rotameter and a nasal catheter or face mask.

High-flow system:
System intended to supply a gas mixture corresponding to the patient's breath. This system is intended to produce a fixed oxygen concentration that is not affected or diluted by the surrounding air, e.g. Venturi mask with a constant oxygen flow in order to give a fixed oxygen concentration in the inhaled air.

Hyperbaric oxygen therapy:
Hyperbaric oxygen therapy (HBO) is given in specially constructed pressurised chambers intended for hyperbaric oxygen therapy, in which pressures up to the equivalent of 3 atmospheres (atm) can be maintained. HBO can also be given via a very tightly fitting facemask, a hood that fits around the head, or through a tracheal tube.

For instructions on handling of the medicinal product before administration, see section 6.6

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 (PaO_2) or haemoglobin oxygen peripheral saturation (SpO_2) 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 $PaCO_2$ 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 (see section 4.2)

In preterm and newborn infants, increased PaO_2 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 insuring 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 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 that 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), 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 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 equipments, 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 (see section 5.3). It is unknown to what extend 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

Different tissues exhibit different sensitivities to hyperoxia, the most sensitive being the lungs, the brain and the eyes.

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 confinement anxiety that is not due to a direct effect of oxygen.

Adverse reactions associated with Oxygen Therapy:

	Very common (> 1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 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) ● Interstitial oedema ● Pulmonary fibrosis Worsening of hypercapnia in patients with chronic hypoxia/hypercapnia treated with too much elevated FiO_2: ● 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:

	Very common (> 1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 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

	Very common (> 1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Very rare (<1/10,000)	Undetermined frequency
Ear and labyrinth disorders	Ear pain		Tympanic membrane rupture			Vertigo Hearing impaired Acute serous otitis media Tinnitus
Gastrointestinal disorders						Nausea
Psychiatric disorders						Abnormal behaviour
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 the national reporting system listed in Appendix V*.

4.9 Overdose

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

Pharmacotherapeutic group:
All other therapeutic products – medical gases, oxygen; ATC code: V03AN01

Oxygen constitutes approx. 21% of air. Oxygen is vital for human life and must be supplied continually to all tissues in order to maintain the cells' energy production. Oxygen is transported in inhaled air via the airways to the lungs. In the pulmonary alveoli, as a result of the difference in partial pressure, gas exchange takes place from the inhaled air/gas mixture to the capillary blood. The oxygen is transported further in the systemic circulation, for the most part bound to haemoglobin, to capillary beds in the various tissues of the body. The oxygen is transported with the aid of the pressure gradient out to the various cells, its goal being the mitochondria in the individual cells, where it takes part in an enzymatic chain reaction, which creates energy. By increasing the oxygen fraction in the inhaled air/gas mixture, the partial pressure gradient that controls the transport of oxygen to the cells increases.

Giving oxygen at a pressure higher than atmospheric pressure (HBO) considerably increases the amount of oxygen that is transported with the blood to the peripheral tissues. Intermittent hyperbaric oxygen therapy causes oxygen transport even within oedematous tissues and tissues with inadequate perfusion, and in this way can maintain cellular energy production and function.
In accordance with Boyle's law, HBO reduces the volume of gas bubbles in tissues in relation to the pressure with which it is given.

HBO counteracts the growth of anaerobic bacteria.

5.2 Pharmacokinetic properties

Inhaled oxygen is absorbed by a pressure-dependent gas exchange between alveolar gas and the capillary blood that passes the alveoli.

Oxygen is transported by the systemic circulation to all tissues in the body, mainly bound reversibly to haemoglobin. Only a very small fraction is freely dissolved in plasma. On passage through tissue, partial pressure-dependent transport of the oxygen to the individual cells takes place. Oxygen is a vital component in the intermediate metabolism of the cell. It is critical to the cell's metabolism, among other things, in order to create energy through the aerobic ATP production in the mitochondria.

Oxygen accelerates the release of carbon monoxide that is bound to haemoglobin, myoglobin and other iron-containing proteins, and thus counteracts the negative blocking effects caused by carbon monoxide binding to iron.

Hyperbaric oxygen therapy further accelerates the release of carbon monoxide, compared with 100% oxygen under normal pressure.

Oxygen that is absorbed in the body is eliminated almost completely as carbon dioxide formed in the intermediate metabolism.

5.3 Preclinical safety data

Animal studies have shown that prolonged continous inhalation of pure oxygen may have harmful effects. Tissue injury can be induced in the lung, eye and central nervous system. Marked variability occurs between the time of onset of pathological changes among different species and among animals of the same species. Hyperbaric oxygen treatment during gestation in mice, rats, hamsters and rabbits led to increased resorptions and foetal abnormalities, and decreased foetal body weights.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years for gas cylinders ≤ 5 litre.
5 years for gas cylinders > 5 litre.

6.4 Special precautions for storage

Storage instructions relating to the medicinal product
This medicinal product does not require any special storage instructions with regard to temperature other than those that apply for gas containers and gas under pressure (see below).
Store gas cylinders in a locked room reserved for medicinal gases (does not apply to a home environment).

Storage instructions relating to gas containers and gases under pressure
Contact with combustible material may cause fire.
Keep away from combustible material.
No smoking.
Risk of explosion in cases of contact with oil and grease.
Must not be exposed to strong heat. If at risk of fire – move to a safe place.
Handle carefully. Ensure that the gas cylinders are not dropped or exposed to knocks.
Keep the cylinder clean and dry. Store in a ventilated place reserved for medicinal gases.
Store and transport with valves closed and, where used, with the protective cap and cover in place.

6.5 Nature and contents of container

The shoulder of the gas cylinder is marked with white paint (oxygen). The body of the gas cylinder is white (medicinal gas).

Container (incl. material) and valves:
Not all pack sizes may be marketed.

1-litre steel gas cylinder with shut-off valve
1-litre steel gas cylinder with shut-off valve with Pin index
1-litre steel gas cylinder with shut-off valve with integrated pressure regulator
1-litre aluminium gas cylinder with shut-off valve
1-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator
1-litre aluminium gas cylinder with shut-off valve with Pin index.
1-litre composite gas cylinder with shut-off valve with integrated manometer/pressure gauge

2-litre steel gas cylinder with shut-off valve.
2-litre steel gas cylinder with shut-off valve with Pin index
2-litre steel gas cylinder with shut-off valve with integrated pressure regulator
2-litre steel gas cylinder with shut-off valve and RPV
2-litre aluminium gas cylinder with shut-off valve
2-litre aluminium gas cylinder with shut-off valve with Pin index

2-litre aluminium gas cylinder with shut-off valve and RPV
2-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator
2-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (Compact)
2-litre aluminium gas cylinder with shut-off valve with integrated digital pressure regulator and flow regulator (TAKEO)
2-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-6 litres/min) (VIPROXAL)
2-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (VIPROXAL)
2-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan)
2-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-6 litres/min) (EzOx).
2-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan Smart).

2.5-litre steel gas cylinder with shut-off valve
2.5-litre steel gas cylinder with shut-off valve with Pin index
2.5-litre steel gas cylinder with shut-off valve and RPV
2.5-litre steel gas cylinder with shut-off valve with integrated pressure regulator
2.5-litre aluminium gas cylinder with shut-off valve
2.5-litre aluminium gas cylinder with shut-off valve with Pin index
2.5-litre aluminium gas cylinder with shut-off valve and RPV
2.5-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator
2.5-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-6 litres/min) (VIPROXAL)
2.5-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (VIPROXAL)

3-litre steel gas cylinder with shut-off valve
3-litre steel gas cylinder with shut-off valve with Pin index
3-litre steel gas cylinder with shut-off valve and RPV
3-litre aluminium gas cylinder with shut-off valve
3-litre aluminium gas cylinder with shut-off valve with Pin index
3-litre aluminium gas cylinder with shut-off valve and RPV
3-litre aluminium gas cylinder with shut-off valve with integrated digital pressure regulator and flow regulator (TAKEO)
3-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (VIPROXAL)
3-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-25 litres/min) (VIPROXAL)
3-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan)
3-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan Smart)

4 litre steel gas cylinder with shut-off valve
4 litre steel gas cylinder with shut-off valve with Pin index
4-litre steel gas cylinder with shut-off valve and RPV
4-litre aluminium gas cylinder with shut-off valve
4-litre aluminium gas cylinder with shut-off valve with Pin index
4-litre aluminium gas cylinder with shut-off valve and RPV

5 litre steel gas cylinder with shut-off valve

5-litre steel gas cylinder with shut-off valve with Pin index
5-litre steel gas cylinder with shut-off valve and RPV
5-litre steel gas cylinder with shut-off valve with integrated pressure regulator
5-litre aluminium gas cylinder with shut-off valve
5-litre aluminium gas cylinder with shut-off valve with Pin index
5-litre aluminium gas cylinder with shut-off valve and RPV
5-litre aluminium/alternative steel gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (Compact)
5-litre aluminium gas cylinder with shut-off valve with integrated digital pressure regulator and flow regulator (TAKEO)
5-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-6 litres/min) (VIPROXAL)
5-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (VIPROXAL)
5-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan)
5-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-6 litres/min) (EzOx).
5-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan Smart)

10-litre steel gas cylinder with shut-off valve
10-litre steel gas cylinder with shut-off valve with Pin index
10-litre steel gas cylinder with shut-off valve and RPV
10-litre steel gas cylinder with shut-off valve with integrated pressure regulator and flow regulator
10-litre steel gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (VIPROXAL)
10-litre steel gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-25 litres/min) (VIPROXAL)
10-litre steel gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan)
10-litre steel gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan Smart)
10-litre aluminium gas cylinder with shut-off valve
10-litre aluminium gas cylinder with shut-off valve with Pin index
10-litre aluminium gas cylinder with shut-off valve and RPV
10-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (Compact)
10-litre aluminium gas cylinder with shut-off valve with integrated digital pressure regulator and flow regulator (TAKEO)
10-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (VIPROXAL)
10-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-25 litres/min) (VIPROXAL)
10-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan)
10-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan Smart)

11-litre steel gas cylinder with shut-off valve
11-litre steel gas cylinder with shut-off valve and RPV
11-litre steel gas cylinder with shut-off valve with integrated pressure regulator and flow regulator
11-litre steel gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan Smart)
11-litre aluminium gas cylinder with shut-off valve

11-litre aluminium gas cylinder with shut-off valve and RPV.
11-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (Compact)
11-litre aluminium gas cylinder with shut-off valve with integrated digital pressure regulator and flow regulator (TAKEO)
11-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan)
11-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan Smart)

15-litre steel gas cylinder with shut-off valve
15-litre steel gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan Smart)
15-litre aluminium gas cylinder with shut-off valve
15-litre aluminium/alt steel gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (Compact)
15-litre aluminium gas cylinder with shut-off valve with integrated digital pressure regulator and flow regulator (TAKEO)
15-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan)
15-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator (0-15 litres/min) (Oyan Smart)

20-litre steel gas cylinder with shut-off valve
20-litre steel gas cylinder with shut-off valve and RPV
20-litre steel gas cylinder with shut-off valve with integrated pressure regulator
20-litre aluminium gas cylinder with shut-off valve
20-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator

40-litre steel gas cylinder with shut-off valve

50-litre steel gas cylinder with shut-off valve
50-litre steel gas cylinder with shut-off valve with integrated pressure regulator
50-litre steel gas cylinder with shut-off valve and RPV
50-litre aluminium gas cylinder with shut-off valve
50-litre aluminium gas cylinder with shut-off valve with integrated pressure regulator and flow regulator
50-litre aluminium gas cylinder with shut-off valve and RPV

12 x 40-litre steel gas cylinders with shut-off valve
10 x 50-litre steel gas cylinders with shut-off valve
15 x 40-litre steel gas cylinders with shut-off valve
12 x 50-litre steel gas cylinders with shut-off valve
20 x 40-litre steel gas cylinders with shut-off valve
20 x 50-litre steel gas cylinders with shut-off valve

Cylinders/bundles filled to 200 bar deliver appr X cubic metres (m^3) gas at atmospheric pressure and 15° C according to the table below:

Cylinder size in litres	1	2	2.5	3	4	5	10	11	15	20	40	50
Cubic metres of gas (m3)	0.2	0.4	0.5	0.6	0.8	1.1	2.1	2.3	3.2	4.2	8.4	11

Bundle size in litres	12x40	10x50	15x40	12x50	20x40	20x50
Cubic metres of gas (m^3)	1.0×10^2	1.1×10^2	1.3×10^2	1.3×10^2	1.7×10^2	2.1×10^2

6.6 Special precautions for disposal and other handling

Instructions for use and handling

General
Medicinal gases must only be used for medicinal purposes.

Different gas types and gas qualities must be separated from each other. Full and empty containers must be stored separately.

Never use oil or grease, even if the cylinder valve is stiff or if the regulator is difficult to connect. Handle valves and matching devices with clean and grease-free (hand cream, etc.) hands.

Use only standard equipment that is intended for medicinal oxygen.

Check that the cylinders are sealed before they are taken into use.

Prior to any use, ensure that a sufficient quantity of product remains to allow completion of the planned administration.

Cylinders equipped with the so called Compact, Viproxal, Takeo and Oyan valves have the pressure regulator incoporated in the valve. A separate pressure regulator is therefore not needed. The Compact, Viproxal, Takeo and Oyan valves have a standard quick connector to be used with specific devices. There is also a separate outlet for continuous flow which may be adjusted to the required administration flow for these valves.

Preparation for use

Remove the seal from the valve before use.

Use only regulators intended for medicinal oxygen. Check that the automatic coupling or regulator is clean and that the gaskets are in good condition.

Never use a tool on a stuck pressure/flow regulator intended to be connected manually, as this can damage the coupling.

Open the cylinder valve slowly – at least half a turn.

Do not try to deal with leakage from the valve or device yourself other than by changing the gasket or O-ring.

In the event of leakage, close the valve and uncouple the regulator. Label defective cylinders, put them aside and return them to the supplier.

Using the gas cylinder

Smoking and open flames are absolutely forbidden in rooms where oxygen therapy is being carried out.

Close down the equipment in the event of fire or if it is not being used.

Carry to safety in the event of fire.

Larger gas cylinders must be transported by means of a suitable type of cylinder trolley. Take special care that connected devices are not inadvertently loosened.

When the cylinder is in use it must be fixed in a suitable support.

For cylinders equipped with integrated valves, the user should be prepared to change the cylinder when the pressure gauge is in the yellow zone and change it when it enters the red zone.

When a small amount of gas is left in the gas cylinder (approx. 2 bar), the cylinder valve must be closed. It is important to leave a little pressure in the cylinder to protect it from contamination.

After use, the cylinder valve must be closed hand-tight. Depressurise the regulator or

connection.

7. MARKETING AUTHORISATION HOLDER

<To be completed nationally>

8. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2009-06-04

10. DATE OF REVISION OF THE TEXT

2024-09-18