There's another side to cluster headache.
One of the most painful of primary headaches, cluster headache is estimated to occur in four out of every 1000 persons in the general population. Treatment relies on the dual principles of acute therapies to abort individual attacks, and prophylactic therapy to prevent or suppress attacks during the cluster. Oxygen is a safe treatment for acute attacks, with the advantages of few or no established side effects, the option to combine with other treatments as well as use several times daily.

Oxygen is one of the most powerful, fast-acting treatments for cluster headache. It also belongs to the few treatment alternatives where efficacy has been shown in double-blind, randomized, placebo-controlled, crossover trials. Studies have shown that inhaling 100% oxygen can abort a cluster headache attack in up to 78% of patients.2

The use of oxygen by inhalation has gained widespread acceptance as a safe and effective treatment of acute attacks of cluster headache. Amongst others:

• The European Federation of Neurological Societies recommends 100% oxygen as the first choice in treating acute cluster headache attacks. It is fast and effective and has no contraindications or side-effects within the recommended dose range.3

• Inhalation of 100% oxygen is a proven method of achieving rapid pain relief during acute cluster headache attacks in 70–82% of patients.2

• Inhaled oxygen at 100% for 15 minutes at the start of the attack has been observed to be safe and effective in aborting a cluster headache attack.2

As a leading provider of medical gases worldwide, Linde Healthcare offers a high quality solution for oxygen therapy for cluster headache, packaged with easy-to-use equipment and efficient delivery logistics and support for better, safer patient care.

* Oxygen therapy is now my first and only choice for the acute treatment of my cluster headaches. It is fast acting, there are no adverse side effects, and if required, I can use it several times a day. With the correct mask and breathing set-up, and if taken as soon as the attack starts, I can often abort the attack within three minutes. Quite simply, when in bout, I could not live without oxygen. * – Peter May
A solution that is easy and safe to administer as much as it is effective in relieving symptoms, Linde Healthcare combines clinical understanding and technical innovation with years of experience in gas-enabled medical therapies, respiratory illness, hospital and homecare. For cluster headache treatment, we provide advice on prescription as well as all the equipment and support patients and prescribers need for successful oxygen therapy.

Serving as a knowledgeable and reliable partner in treating cluster headache patients, Linde Healthcare can advise on local regulations for pharmaceutical oxygen and the selection of an appropriate therapy package. We’ll deliver all necessary equipment to the home and provide instruction on handling and use. Patients receive ongoing support, with oxygen refills and equipment maintenance.

Acute attacks are not predictable and can occur anytime, anywhere. Sufferers need a solution that is not only fast-acting and efficient, but also safe, portable and easy to use on the move. We offer an all-in-one package specifically for the treatment of cluster headaches, consisting of high quality medicinal oxygen combined with an O2PTIMASK and practical carry-pack for mobility and convenience.

Treatment device.
Equipment offered by Linde Healthcare includes a non-re-breathing high concentration oxygen mask system (O2PTIMASK) that is intended to allow a spontaneously breathing pattern by inhaling high oxygen concentrations.

The 1-Piece connector used at this high concentration oxygen mask system contains two directional valves that ensure 100% oxygen is inhaled and exhaled and ensures breath containing carbon dioxide passes out the exhaust port and not into the reservoir bag.

The O2PTIMASK is assembled from separate CE marked devices to form a mask, 1-way valve and breathing bag with connection to an oxygen supply.

The O2PTIMASK can be configured with a face mask or mouthpiece according to user preferences. Both configurations are equally effective.

Linde Healthcare offers a wide range of oxygen cylinders. Available designs include 2-litre cylinders and composite lightweight bottles filled with compressed oxygen. A convenient, easily portable 2-litre cylinder filled at 200 bar, for example, provides around 60 minutes of oxygen therapy, enough for 3-4 cluster headache attacks. A Demand Valve device allows for deep breathing without wasting oxygen.

Medicinal oxygen.
Pharmacetically approved medicinal oxygen means adherence to the same high requirements that govern all other pharmaceutical products, including pharmacovigilance and traceability.

"I simply wouldn’t survive without constant access to oxygen therapy. How do you survive 6-7 attacks per 24 hours when you can only inject twice? Oxygen therapy is the main weapon for me to reach that next “injection window.” It also enables me to get out of the house. I am self-employed and my work takes me all around the country. Therefore, no oxygen, no job!! Finally, thanks to the wonderful service provided by the oxygen companies around the country we have been able to enjoy a couple of much needed holidays." – Sean Kelly
There’s another side to cluster headache.

Oxygen therapy for cluster headache has a number of clear advantages: effective abort of pain, fast-acting, few side effects and unlimited use. In addition, Linde Healthcare’s unique solution for control of administration as well as reliable logistics for the delivery of equipment and related patient services assures quality and continuity of care.

Speed is essential in treating cluster headache given the intensity of the pain, due to the suddenness of the onset and the fact that attacks are usually short-lived. Fast-acting relief is imperative for acute attacks. Oxygen is effective after as little as 15 minutes in most cases. As cluster headache attacks can occur up to 8 times a day, sufferers rely on a therapy that can provide relief a number of times during the day. Most common drugs can only be taken at designated windows. Oxygen therapy can be used multiple times a day, used as a standalone treatment or combined with other medication to treat attacks that occur between designated windows.

For the brighter side of life.

Benefits of oxygen therapy for cluster headache.

- Fast-acting therapy with relief after as little as 15 minutes.
- Can be administered several times daily.
- No side effects or contraindications within the recommended dose range.
- Ideal in combination with prophylactics.

Safe.
Used in the prescribed quantities, oxygen causes no side effects. It can be used during pregnancy and breastfeeding. It can also be prescribed for patients with cardiac, cerebral or peripheral vascular disease as well as patients with kidney, liver or lung disease. The presence of COPD should be checked as this could lead to respiratory suppression caused by a history of chronic carbon dioxide retention. With treatment duration of only 15–20 minutes for inhaled oxygen, toxicity is extremely unlikely to be experienced. Using more than the prescribed amount of medicinal oxygen may affect respiratory function and in exceptional cases result in carbon monoxide narcosis/loss of consciousness. Prolonged use of excess medicinal oxygen is liable to cause pain, dry cough and breathlessness.

Technical developments in delivery devices over the recent years have solved many of the safety issues involved with oxygen treatment in the home. As an additional measure, Linde Healthcare provides patients with comprehensive guidance regarding safe usage.

02TIMASK

"It’s episodic and because of oxygen I don’t have to dread the onslaught quite as much as pre-oxygen years. It was like waiting for the axe to fall. It still is I suppose but at least now I can do stuff and go places while I’m in cycle. Before oxygen I didn’t dare plan anything, life simply came to a stop and was pure misery for the entire episode. Oxygen helps you to keep your life going."

– Dorothy Chapman

For the brighter side of life.
Summary of Product Characteristics.

Cluster headache is an approved indication of medicinal oxygen in the following countries: AR, AT, NL, LU, CZ, DK, EE, FI, FR, HU, LV, LT, PL, ES, IS, SE, SK, ZA, NY.

1. Name of the medicinal product: Medيكlinic Oxygen AHA 100%. Medicinal gas, compressed.

2. Qualitative and quantitative composition: Oxygen 100% at a pressure of 280 bar (15°C), Oxygen 100% at a pressure of 153 bar (15°C), 21.3 litre cylinder and bundle 2x21,3 litre.


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 rebreathing treatment.
- As first aid treatment with 100% oxygen in decompression accidents.
- 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 carbon dioxide value.

As adjunct treatment in: severe osteoradionecrosis, ostitis myositis ossificans (gas gangrene).

4.2 Posology and method of administration:

Method of administration:
Oxygen therapy: Oxygen is administered via the inspiratory air.
Oxygen can also be supplied through a so-called ‘rebreather’ directly to the blood in cases of, among other things, cardiac surgery with a ‘oxygenator’ directly to the blood in cases of, among other things, cardiac surgery with a ‘oxygenator’ directly to the blood in cases of.

Oxygen is administered via the inspiratory air.

4.3 Contraindications:

There is no absolute contraindication to oxygen therapy. Hyperbaric oxygen treatment should be used with caution during pregnancy and in females of child bearing potential (see 4.6).

4.2 Special warnings and precautions for use:

High concentrations of oxygen in vulnerable sections of the lungs; the ventilation/perfusion ratio can occur (development of atelectasis). The ventilation/perfusion ratio can be considered negligible if

- The inspired oxygen fraction (FIO2) 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 (FIO2) 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 PaO2 or arterial oxygen saturation (SpO2).

In short-term treatment with oxygen, the oxygen concentration -the fraction in the inhaled gas mixture (FiO2), (FiO2 > 80%) in the inhaled gas mixture - must be kept so that, with or without end-expiratory pressure (EEP) or continuous positive airway pressure (CPAP), an arterial oxygen pressure (PaO2) - 8 kPa can be achieved.

In the emergency/acute setting the usual dose for adults to treat or prevent acute oxygen deficiency is 3-5 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 gauged by the result of arterial blood gas measurements. For adjusting oxygen therapy in patients with hypercapnia, arterial blood gas measurements 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 (FiO2) must not be lower than 21% and may be up to 100%.

Administration of pure oxygen (FiO2, 1.0) in the early management of divers exhibiting signs and/or symptoms of diving disease facilitates the diffusion/elimination of nitrogen from the blood and tissues subsequently resulting in reduction of nitrogen bubbles and gas emboli.

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

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 patient has disappeared. Usually a flow of 7 to 10 ml/ min but up to 15 ml/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 atmospheric pressure at sea level (1 atmosphere = 1013 kPa = 760 mmHg). For safety reasons the pressure in HBO should not exceed 3 atmospheres. The duration of a single HBO 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.

Repeated 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 gangrenous 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).

In hyperbaric oxygen therapy, the pressure should be increased and reduced slowly in order to avoid the risk of pressure damage (barotrauma).

Hyperbaric oxygen treatment should be used with caution during pregnancy and in females of child bearing potential (see 4.6).

HBO should be used with caution in patients presenting with pneumothorax.

4.5 Interaction with other medicinal products and other forms of interaction:

The pulmonary toxicity associated with drugs such as bleomycin, amiodarone, furadantin and similar antibiotics, may be exacerbated by inhalation of increased concentration of oxygen.

4.6 Pregnancy and lactation:

Oxygen can be used during pregnancy and lactation.

Hyperbaric oxygen treatment should be used with caution during pregnancy and in females of child bearing potential due to a potential risk of oxidative stress-induced damage in the fetus. In severe carbon monoxide intoxication the benefit vs. risk seems reassuring for the use of hyperbaric oxygen treatment. The use should then be evaluated in each individual patient.

4.7 Effects on ability to drive and use machines:

In normal circumstances, medicinal oxygen does not interfere with level of consciousness.

Patients who require continuous oxygen support should be evaluated on an individual basis, taking their entire medical situation into account for evaluating if it is recommendable to drive and/or operate complex machinery.

4.8 Undesirable effects:

Common (>1/100, <1/10):

- None.

Rare (<1/1000, <1/100):

Eye disorders: Retinoblastoma in neonates exposed to high oxygen concentrations.

Very rare (<1/10,000):

- Respiratory, thoracic and mediastinal disorders: Aphale, Meagitis.

Hyperbaric oxygen treatment Central nervous system: Anxiety, Confusion, Loss of consciousness, Epilepsy unanaplated.

4.9 Overdose:

Oxides of oxygen do not occur outside treatment in intensive care, and the risks of these are greater with hyperbaric oxygen therapy.

In oxygen intoxication, (symptoms of oxygen toxicity), the oxygen therapy should be reduced or impossible stopped, and symptomatic treatment should be started in order to maintain vital functions (e.g. artificial ventilation/assisted ventilation should be given if the patient shows signs of failing respiration).

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Pharmaco-therapeutic group:
All other therapeutic products – medical gases, Pharmaco-therapeutic group: Medical gases.

5.2 Pharmacokinetic properties:

Oxygen constitutes approx. 21% of air. Oxygen is vital for human life and cellular energy production. Oxygen is transported...
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 with the aid of the pressure gradient out to the blood. The oxygen is transported further in the from the inhaled air/gas mixture to the capillary in partial pressure, gas exchange takes place.

5.3 Preclinical safety data. Animal studies have shown that prolonged continuous 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 fetal abnormalities, and decreased fetal body weights.

5.4 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). In Ireland, the body of the gas cylinder can also be turquoise.

In accordance with Boyle’s law, HBO reduces the volume of gas bubles in tissues in relation to the pressure with which it is given. HBO counteracts the growth of anaerobic bacteria.

5.2 Pharmacodynamic properties. Inhaled oxygen is absorbed by a pressure- dependent gas exchange between alveolar gas and the capillary blood that passes the alveolus. Oxygen is transported by the systemic circulation to all tissues in the body, mainly bound reversibly to haemoglobin. Only a very small proportion 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.

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 oxygen or gas, even if the cylinder valve is still or if the regulator is difficult to connect. Handle valves and devices to match 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 the sufficient quantity of product remains to allow completion of the planned administration.

Cylinders equipped with the so called LIV valve have the pressure regulator inoperated in the valve. A separate pressure regulator is therefore not needed. The LIV valve has a standard quick connector to be used with specific devices. There is also a separate outlet for continuous flow which may be adjusted to required administration flow.

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.

Check for leakage in accordance with the instruction that accompanies the regulator. Do not try to deal with leakage from the valve or device yourself other than by changing the gasket at 0-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. AAGA AB
SE-181 81 Lidingö, Sweden

8. Marketing authorisation number(s).

18687

9. Date of first authorisation/ renewal of the authorisation.

2005-08-04 / 2010-08-04

10. Date of revision of the text.

29 October 2010
Linde: Living healthcare

Every day, Linde Healthcare helps over hundreds of thousands of patients cope with respiratory illness in their homes, at work and while travelling. We bring the same commitment and expertise to sufferers of cluster headache.

Linde Healthcare is dedicated to providing products, therapies and services to hospitals, clinics, nursing facilities, emergency management services and home healthcare providers around the world. With over a century of working closely with our customers, we have established a solid foundation as a healthcare partner with medical gas expertise and combine our knowledge of healthcare realities with continuous research and development. We are present in 70 countries around the world, working to ensure our solutions are always delivered and serviced to the highest possible standards of quality and safety.

References.

5. Kudrow L: Response of cluster headache attacks to oxygen inhalation. Headache 1981; 21(1):1-4, and this has been confirmed in a small, controlled study.