Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Medical Oxygen, 100% inhalation gas

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxygen Ph Eur 100%v/v

Consists solely of compressed oxygen conforming to the requirements of the monograph of the European Pharmacopoeia.

There are no other ingredients

3. PHARMACEUTICAL FORM

Inhalation Gas

A colourless, odourless and tasteless gas supplied under pressure in cylinders

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

At high concentrations in the treatment of acute severe asthma, pulmonary thrombo-embolism, pneumonia and fibrosing alveolitis.

For the treatment of carbon monoxide poisoning.

To reduce the volume of air trapped in body cavities, as for example, in patients with pneumothorax and air embolism. Inhalation of air containing a high concentration of oxygen (and hence low concentration of nitrogen) enhances removal of trapped nitrogen.

As a diluent or carrier gas in anaesthesia.

4.2 Posology and method of administration

Posology

High concentration oxygen therapy, with concentrations up to 60% for short periods is safe for conditions like pneumonia, pulmonary thrombo-embolism 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% and even 24% may be excessive in some patients.

Oxygen may be administered at concentrations of up to and including 100% though with most delivery systems inspired concentrations over 60% (80% in children) are unlikely to be achieved. In practice 30% 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.

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.

Method of administration

Medical Oxygen is administered via inspiratory air

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 bellow the concentration in air. In practice 30% is usually taken as a lower limit, with allowance for a safety margin.

Instructions for Use

GENERAL

1. 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 and the correct operating procedures for their installation.
2. If you own your own cylinders, you must be aware of and discharge your statutory obligations with regard to maintenance and testing.
3. Ensure that when cylinders are collected the driver has been properly instructed in the method of handling cylinders and in dealing with any emergency.

STORAGE OF CYLINDERS

1. Cylinders should be stored under cover, preferably inside, kept dry and clean and not subjected to extremes of heat or cold.
2. Cylinder should not be stored near stocks of combustible materials or near sources of heat.
3. Warning notices prohibiting smoking or naked lights should be posted clearly.
4. Emergency services should be advised of the location of the cylinder store.
5. Medical cylinders containing different gases should be segregated within the store.

6. Full and empty cylinders should be stored separately. Full cylinders should be used in strict rotation.
7. Medical cylinders should be stored separately from industrial and other non-medical cylinders.
8. Cylinders must not be repainted, have any markings obscured or labels removed.
9. Precautions should be taken to protect cylinders from theft.

PREPARATION FOR USE

1. Cylinder valves must be opened slowly.
2. Cylinder valves should be opened momentarily prior to use to blow any grit or foreign matter out of the outlet.
   Ensure that the connecting face of the pin index yoke, or regulator is clean and the sealing washer or 'O' ring where fitted is in good condition.
3. Where an integral valve is not used only the appropriate regulator should be used for the particular gas concerned.
4. Pipelines for medical gases should be controlled in accordance with the conditions set out in HTM 02.
5. Cylinder valves and any associated equipment must never be lubricated and must be kept free from oil and grease.

LEAKS

1. Should leaks occur, this would usually be evident by a hissing noise.
2. Leaks can be found by brushing the suspected area with an approved leak detection solution
3. Sealing or joining compounds must never be used to cure a leak.
4. Never use excessive force when connecting equipment to cylinders.

USE OF CYLINDERS

1. Cylinders should be handled with care and not knocked violently or allowed to fall.
2. Cylinders should only be moved with the appropriate size and type of trolley.
3. When in use, cylinders should be firmly secured to a suitable cylinder support.
4. Medical gases must only be used for medicinal purposes.
5. Smoking and naked lights must not be allowed within the vicinity of cylinders or pipeline outlets.
6. After use, cylinder valves should be closed using moderate force only and the pressure in the regulator or tailpipe released.
7. When empty, the cylinder valve must be closed.
8. Immediately return empty cylinders to the empty cylinder store for return to Medical Gas Solutions Ltd.

4.3 Contraindications

1. High concentrations of oxygen are contra-indicated in chronic severe airways disease and premature neonates
2. Patients should not smoke while on oxygen therapy because of the fire risks

4.4 Special Warnings and Precautions for Use

Patients with chronic severe obstructive airways disease rely on hypoxic drive for respiration. When such patients are given oxygen therapy it must be administered at a relatively low concentration and must be accurately metered and titrated against arterial concentrations and clinical observation.

Connections for hoses, valves etc. must be clean and dry. If necessary, clean only with plain water. Do not use solvents. Use clean, lint free cloths for cleaning and drying off.

Use no oil or grease on valve or associated equipment. Do not allow naked flames near the container. Do not smoke when using oxygen. Do not breathe oxygen at pressures in excess of atmospheric.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions with amiodarone have been reported. Relapse of bleomycin-induced lung disease may be associated with a fatal outcome.

Patients with pre-existing oxygen radical damage to the lung may have this damage exacerbated by oxygen therapy e.g. in the treatment of paraquat poisoning.

Respiratory depression due to alcohol may potentiate that caused by oxygen.

4.6 Fertility, pregnancy and lactation

There are no contraindications for oxygen therapy during pregnancy or breast-feeding or any effect on fertility that is known

4.7 Effects on ability to drive and use machines

Oxygen therapy at ambient pressure has no adverse effect on the ability of the patient to drive and operate machinery.

4.8 Undesirable effects

In patients with chronic severe airway disease who rely on hypoxic drive of respiration, the administration of high levels of oxygen will result in further under-ventilation and further accumulation of carbon dioxide and acidosis.

In the premature infant exposure to excessive oxygen concentrations may be associated with the following conditions: retrolental fibroplasia, bronchopulmonary dysplasia, subependymal and intraventicular haemorrhage and necrotising enterocolotis.

CNS oxygen toxicity only occurs when the partial pressure of inspired oxygen exceeds 2 atmospheres (203 kPa), that is in hyperbaric oxygen therapy.

Hyperbaric oxygen treatment has been shown in some studies to be linked with hyperbaric Oxygen-induced oxidative DNA damage that can lead to gross genetic alterations and chromosome aberrations after hyperbaric oxygen under therapeutic conditions. It has also been shown that a single hyperbaric oxygen exposure induced adaptive protection against further induction of oxidative DNA damage. Cases must be assessed individually and the therapy protocol may consider a shortened treatment before the standard protocol is applied.

4.9 Overdose

Prolonged hyperoxygenation can result in lung injury. Cases must be assessed individually, but experience from healthy volunteers would suggest that prolonged exposure, over periods of months, to concentrations up to 30% whilst producing sub-clinical pathologic changes has not been proven to cause specific lung injury. Similarly for exposures up to 60% for up to one week. However administration of 100% oxygen for more than 24 to 30 hours will result in substernal chest pain and mild dyspnoea. Symptoms may progress, become systemic and include malaise, nausea and transient paraesthseia.

See section 4.8 for the effects of over dose in specific patient groups.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group - Medical Gas.
ATC Code - V03AN01.

The characteristics of medical oxygen are: odourless, colourless gas

Oxygen is present in the atmosphere at 21% and is an essential for life .Oxygen must be supplied continuously to all body tissues in order to maintain the cells' energy production. Oxygen is transported via the airways to the lung with the inspired air. Gas exchange takes place in the alveoli through the difference in partial pressure from the inspired air/gas mixture to the capillary blood. The oxygen is transported in the blood, mainly bound to haemoglobin, to the capillary bed in tissue where it is transported by the pressure gradient to the difference cells. In the mitochondria in the individual cells the oxygen is consumed in an enzymatic chain reaction forming energy. By increasing the oxygen fraction in inspired air the partial pressure gradient transporting oxygen to the cells is increased

5.2 Pharmacokinetic properties

The inhaled oxygen is taken up be a pressure dependent gas exchange between alveoli gas and the capillary blood that passes the alveoli. The oxygen is transported to all tissues in the body. A partial pressure dependent transport of the oxygen to the individual cells takes place. Oxygen is a vital component in the cell's intermediate metabolism for the creation of energy (the aerobic ATP production in the mitochondria)

5.3 Preclinical Safety Data

The published toxicological-pharmacological data indicates that medical oxygen is not harmful to humans

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

There are no excipients

6.2 Incompatibilities

There are no known incompatibilities with oxygen.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Storage area to be free from oil or grease. Segregate from flammable gases and other flammable materials in store. Keep container below 50 C and not subject of temperature extremes, in a well ventilated place. Keep storage area free from debris. Medical cylinders containing different gases to be segregated and identified. Medical cylinders not to be stored with other types of cylinders. Full cylinders should be used in strict rotation and full and empty cylinders separated

6.5 Nature and contents of container

Medical Oxygen 100%, Inhalation Gas is a compressed gas that is held within a pressure vessel made of a limited list of materials. These can include steel, aluminium, aluminium liners with carbon wrap on either the sides of the cylinder or all over. The cylinders conform to the requirements set out in the current Carriage of Dangerous Goods and the Transportable Pressure Equipment Regulations. All cylinders used for Medical Oxygen 100% Inhalation Gas are designed and tested to conform to these regulations.

Medical Oxygen 100% Inhalation Gas cylinders are fitted with a valve; the valve can be a pin-index valve conforming to BS EN 407, a bullnose valve that complies with BS 341 or an integral pressure regulator valve that is CE marked for Medical Device regulations

The cylinders have a variety of water capacities ranging from 0.5 to 68 litres and are filled to 137, 200, 230 or 300 bar.

This gives the following range of nominal oxygen content in litres of the cylinders at 15 C and 1013.2 mbar:

75,110, 150, 170, 215, 220, 240, 250, 300, 305, 320, 340, 365, 395, 425, 440, 485, 495, 540, 580, 610, 640, 680, 725, 730, 915, 1000, 1070, 1360, 1460, 2010, 2130, 2420, 3050, 3400, 5035, 6800, 7280, 10025, 10660, 20800

The colour scheme for Medical Oxygen cylinders is changing from a black body with a white shoulder (top) to a white body with a white shoulder (top).
Your cylinder may be of either colour scheme.

6.6 Special Precautions for Disposal

Contact Medical Gas Solutions to refill the cylinder. Any cylinders that are no longer required should be returned to Medical Gas Solutions

7. MARKETING AUTHORISATION HOLDER

Medical Gas Solutions Ltd
Unit 19 Manor Industrial Park
Bagillt
Flint. CH6 5UY

8 MARKETING AUTHORISATION NUMBER(S)

PL 17872/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st July 2011

10 DATE OF REVISION OF THE TEXT

11th December 2014