SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Medical Liquid Oxygen [oxygen Ph Eur]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Consists solely of Medical Liquid Oxygen which on evaporation yields gaseous oxygen conforming to the requirements of oxygen PhEur.

3. PHARMACEUTICAL FORM

Medicinal gas [on evaporation of the liquid].

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

(2) For the treatment of carbon monoxide poisoning.

(3) 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 a low concentration of nitrogen) enhances removal of trapped nitrogen.

(4) As a diluent or carrier gas in anaesthesia.

4.2 Posology and Method of administration

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. 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 [21 %]. 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, tents, cot hoods and supply to a tracheostomy. In severe hypoxia the use of a positive pressure mask may be valuable. The technique should only be used by experienced practitioners.

4.3 Contra-Indications

(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 fire risks.

4.4 Special Warnings And Special Precautions For Use

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

Note that contact with Medical Liquid Oxygen can cause burns. Avoid such contact by wearing protective clothing. Eye protection and suitable gloves should always be worn with full-length outer garments [full-length trousers

without turn-ups and full-length rolled-down sleeves] so as to facilitate safe and correct usage and handling.

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 container. Do not smoke when using oxygen. Do not breath oxygen at pressures in excess of atmospheric.

4.5 Interactions 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 Pregnancy and Lactation

There are no contra-indications for oxygen therapy during pregnancy or breast-feeding.

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 or 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 neonate, exposure to excessive oxygen concentrations may be associated with the following conditions: retrolental fibroplasia, bronchopulmonary

dysplasia, sub-ependymal and intraventricular haemorrhage and necrotising enterocolitis.

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

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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. The same applies for exposure at up to 60% oxygen, for up to 1 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 paraesthesia.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

Through evolution, the oxidative production of energy has been associated with the development of mechanisms for defence against oxidative damage. When these mechanisms are overwhelmed by prolonged over-oxygenation, tissue damage will occur, and this is particularly marked in the lungs which are generally exposed to the highest concentrations of oxygen. Other sites susceptible to oxidative damage include the CNS and retina, as discussed above.

Oxygen in inspired air enters the lungs and diffuses across the walls of the alveoli and surrounding blood capillaries and then enters the blood which transports it throughout the body. This is a normal physiological process, essential for survival.

5.2 Pharmacokinetic Properties

Not applicable

5.3 Preclinical Safety Data

Not applicable

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

7 days. Shelf-life is determined by the rate of natural evaporation of gas from the container and not by deterioration of the product.

6.4 Special Precautions for Storage

Storage area to be free from oil and grease. Segregate from flammable gases and other flammable materials in store. Keep away from ignition sources, including static discharges and sources of heat. Keep containers below 50°C and not subject to temperature extremes, in a well-ventilated place. Keep storage area free of debris. Medical cylinders containing different gases are to be segregated and identified. Medical cylinders are not to be stored with other

types of cylinder. Full cylinders should be used in strict rotation and full and empty cylinders separated. Cylinders must be stored vertically.

6.5 Nature and Contents of Container

Stainless steel cryogenic gas cylinder or storage tank fitted with safety valve and controlled outlets for the removal of either gaseous or Medical Liquid Oxygen as required.

6.6 Instructions for Use, Handling and Disposal

Use in accordance with the doctor's instructions.

Contact with Medical Liquid Oxygen can cause burns. Ensure that the container is upright at all times during use and handling. Avoid contact by wearing protective clothing. Eye protection and suitable gloves should always be worn with full-length outer garments [full-length trousers without turn-ups and full-length rolled-down sleeves] so as to facilitate safe and correct usage and handling.

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.

7 MARKETING AUTHORISATION HOLDER

Air Products PLC
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Westmere Drive
Crewe
Cheshire CW1 6AP

8. MARKETING AUTHORISATION NUMBER

PL 06183/0001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Authorisation renewed 05 May 1994

10 DATE OF REVISION OF THE TEXT

01/11/2019