SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Medical Oxygen (Oxygen Ph Eur)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

3. PHARMACEUTICAL FORM

Inhalation 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.

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

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 bellow 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 tracheotomy.

In severe hypoxia the use of a positive pressure mask may be valuable. This 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 the fire risks.

4.4. Special Warnings and Special 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.

Note that contact with liquid oxygen can cause burns. Avoid such contact by wearing protective clothing. Eye protection and suitable gloves should 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 the container. Do not smoke when using oxygen. Do not breathe 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 contraindications 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 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 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 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. 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 sub sternal 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 over dose 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.

5.2. Pharmacokinetic Properties

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 normal physiological process, essential for survival.

5.3. Pre-clinical 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

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. Cylinders are intended to be stored vertically.

6.5 Nature and contents of container

Not all pack sizes may be marketed.

The gas cylinder is constructed of high-strength chromium-molybdenum steel fitted with a valve. Cylinders are colour coded in accordance with BS EN1089-3.

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

The following is a list of the nominal oxygen content of the cylinders at 15 C and 1013.2 mbar:

74, 81, 88, 97, 103, 107, 113, 118, 129, 132, 145, 147, 150, 154, 161, 162, 171, 176, 177, 184, 185, 191, 193, 201, 206, 210, 214, 216, 221, 226, 235, 236, 242, 247, 250, 257, 258, 265, 268, 274, 277, 279, 290, 294, 300, 306, 308, 309, 322, 323, 338, 339, 343, 353, 355, 364, 368, 370, 371, 382, 385, 386, 387, 397, 401, 403, 407, 412, 419, 426, 429, 432, 435, 441, 450, 451, 456, 462, 467, 470, 472, 484, 485, 493, 500, 514, 515, 516, 524, 529, 532, 536, 544, 548, 555, 557, 559, 564, 573, 579, 580, 586, 588, 596, 600, 603, 613, 617, 622, 629, 632, 643, 645, 647, 661, 662, 665, 676, 677, 678, 686, 691, 693, 706, 707, 709, 720, 725, 729, 735, 740, 741, 750, 758, 764, 771, 772, 774, 779, 790, 793, 794, 802, 806, 809, 815, 822, 823, 832, 836, 838, 853, 854, 857, 863, 867, 870, 879, 882, 887, 894, 897, 900, 903, 911, 919, 922, 925, 926, 935, 941, 943, 951, 956, 965, 967, 970, 983, 985, 986, 987, 999, 1000, 1007, 1014, 1015, 1017, 1029, 1032, 1044, 1048, 1050, 1058, 1064, 1072, 1073, 1079, 1080, 1088, 1093, 1096, 1103, 1110, 1112, 1115, 1117, 1128, 1132, 1136, 1141, 1144, 1147, 1158, 1161, 1172, 1176, 1177, 1179, 1191, 1193, 1200, 1202, 1205, 1209, 1220, 1222, 1225, 1233, 1235, 1241, 1243, 1250, 1257, 1264, 1265, 1273, 1279, 1286, 1290, 1294, 1295, 1306, 1308, 1322, 1323, 1326, 1329, 1338, 1350, 1352, 1354, 1357, 1367, 1370, 1372, 1382, 1386, 1387, 1393, 1397, 1402, 1411, 1415, 1418, 1426, 1435, 1436, 1441, 1449, 1451, 1455, 1458, 1467, 1470, 1479, 1480, 1483, 1499, 1501, 1511, 1515, 1520, 1522, 1531, 1542, 1543, 1547, 1564, 1565, 1572, 1580, 1586, 1596, 1603, 1608, 1612, 1629, 1634, 1651, 1665, 1672, 1693, 1696, 1715, 1727, 1736, 1757, 1758, 1779, 1788, 1801, 1819, 1822, 1844, 1850, 1865, 1881, 1886, 1908, 1912, 1929, 1942, 1951, 1972, 1973, 1994, 2004, 2015, 2021, 2035, 2036, 2058, 2066, 2079, 2097, 2101, 2122, 2127, 2144, 2158, 2189, 2220, 2251, 2281, 2312, 2343, 2374, 2405, 2436, 2466, 2497, 2528, 2559, 2590, 2621, 2651, 2682, 2713, 2744, 2775, 2806, 2836, 2867, 2898, 2907, 2929, 2960, 2991, 3021, 3052, 3083, 3469, 3804, 5059, 6939, 7276, 7608, 10118, 14552

6.6. Instructions for Use, Handling and Disposal

Use in accordance with the doctor’s instruction.

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. 10 litre size cylinders and larger should be stored vertically. 5 litre size cylinders and smaller should be stored horizontally.

10. Precautions should be taken to protect cylinders from theft.

PREPARATION FOR USE

1. Cylinder valves should be opened momentarily prior to use to blow any grit or foreign matter out of the outlet.

2. Ensure that the connecting face of the yoke, manifold or regulator is clean and the sealing washer or ‘O’ ring where fitted is in good condition.

3. Cylinder valves must be opened slowly.

4. Only the appropriate regulator should be used for the particular gas concerned.

5. Pipelines for medical gases should be controlled in accordance with the conditions set out in HTM 2022.

6. 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. The gland packing around the valve spindle may become loose and can be cured by tightening the gland nut clockwise. Do not over tighten.

4. Sealing or joining compounds must never be used to cure a leak.

5. 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. Ensure the plastic valve cap is refitted to bullnose valves/outlets.

9. Immediately return empty cylinders to the empty cylinder store for return to Air Products.

7 MARKETING AUTHORISATION HOLDER

Air Products PLC
Millennium Gate 2
Westmere Drive
Crewe
Cheshire CW1 6AP

8. MARKETING AUTHORISATION NUMBER(S)

PL 06183/0011

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

30th June 1997

10 DATE OF REVISION OF THE TEXT

20/11/2020