

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Medical Oxygen

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxygen Ph Eur 100%.

Consists solely of compressed oxygen.

There are no other ingredients.

## 3 PHARMACEUTICAL FORM

Medicinal gas, compressed.

A colourless, odourless and tasteless gas supplied as a compressed gas 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.
- At low concentrations in the treatment of ventilatory failure due to chronic obstructive airways disease and other causes.
- For the treatment of carbon monoxide poisoning.
- To reduce the volume of air trapped in body cavities, as for example, in patients with pneumothorax, air embolism and decompression sickness. Inhalation of air containing a high concentration of oxygen (and hence low concentration of nitrogen) enhances removal of trapped oxygen.
- Pulmonary oedema.
- As a diluent or carrier gas in anaesthesia.
- Other indications include cystic fibrosis, shock, severe anaemia, sleep apnoea, cluster headaches and anaerobic infections.

### 4.2 Posology and method of administration

High concentration oxygen therapy, with concentrations up to 60% for short periods is safe for conditions like acute severe asthma, pulmonary thrombo-embolism, pneumonia 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%.

Oxygen may be administered at concentrations of up to and including 100% although with most delivery systems inspired concentrations over 60% (80% in children) are unlikely to be achieved. In practice 24% 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. 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 tracheostomy.

In severe hypoxia the use of a positive pressure mask may be valuable. This technique should only be used by experienced practitioners.

### **4.3 Contraindications**

Oxygen supports combustion and smoking should be prohibited when oxygen is in use and no naked flames should be allowed.

### **4.4 Special warnings and precautions for use**

There are no absolute contraindications to the use of oxygen but inspired concentrations should be limited in the case of premature infants and those patients with chronic airways disease.

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. There is need to limit inspired oxygen concentrations in premature infants because of the risk of retinopathy of prematurity.

High concentrations of oxygen should always be reduced as soon as possible to the lowest concentrations needed to correct hypoxia, in order to prevent the development of any associated oxygen toxicity.

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 the cylinder 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.

In spite of the various hazards associated with oxygen the benefits of treatment will often far outweigh the risks. Those risks can be minimised by titrating oxygen supply to the needs of the individual patient.

The danger of oxygen and fire cannot be over-emphasised. The risk of fire and serious burns should always be stressed to patients receiving oxygen therapy. Whilst oxygen is non-flammable it strongly supports combustion. Thus smoking is prohibited when oxygen is in use and no naked flame should be allowed. Since even the smallest spark can cause violent ignition, electrical equipment capable of sparking (including even toys which may produce sparks) should not be used in the vicinity of patients receiving oxygen.

It is very important also that the reducing valve that controls the flow rate is free from all traces of oil and grease since otherwise there is a risk of spontaneous combustion and a violent explosion may occur.

## 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.

## 4.7 Effects on ability to drive and use machines

In normal circumstances, oxygen does not interfere with conscious level but patients who require continuous oxygen support will require individual assessment as to their ability 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 infant exposure to excessive oxygen concentrations may be associated with the following conditions: retrolental fibroplasia, bronchopulmonary dysplasia, subependymal and intraventricular haemorrhage and necrotising enterocolitis.

In hyperbaric chambers in the management of conditions such as carbon monoxide poisoning, anaerobic infections and acute ischaemic diseases, convulsions and other central nervous system (CNS) effects may occur at 2 atmospheres or more, after a few hours exposure to pure oxygen. At higher pressures more rapid onset of CNS symptoms will occur.

Oxygen toxicity depends upon both the inspired pressure (a function of concentration and barometric pressure) and the duration of exposure, the safe duration decreasing as the pressure increases.

At lower pressures of up to 2 atmospheres absolute, pulmonary toxicity occurs before CNS toxicity; at higher pressures the reverse applies. Symptoms of pulmonary toxicity include a decrease in vital capacity, cough and substernal distress. Symptoms of CNS toxicity include nausea, mood changes, vertigo, twitching, convulsions and loss of consciousness. Retinopathy of prematurity (retrolental fibroplasia) has been associated in some premature infants with excessive 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

## 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 paraesthesia.

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

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

The characteristics of

oxygen are:

Odourless, colourless gas.

Molecular weight 32.00

Boiling point -183.1 degrees Celsius (at 1 bar)

Density 1.355kg/m<sup>3</sup> (at 15° Celsius)

Oxygen is present in the atmosphere at 21% and is an absolute necessity for life.

The basal oxygen consumption in man is about 250ml/min for a body surface of 1.8sq metres. It is reduced by about 10% during anaesthesia and natural sleep and by about 50% for a 10 degree Celsius fall in body temperature.

Alveolar air contains about 15% oxygen at 14 kpa (105mm Hg) and arterial blood has an oxygen tension of 13 kpa (97mm Hg).

The difference, known as the alveolar-arterial oxygen tension gradient, increases with age. The difference may be as great as 4kpa (30mm Hg) in a healthy, elderly individual.

Oxygen in the blood is mostly combined with haemoglobin. Normally, haemoglobin in arterial blood is 97% saturated and the oxygen content of the blood is 19.8 vol%, 0.3ml of this being carried in solution. The remainder is held in chemical combination with haemoglobin.

The concept of oxygen availability can be expressed as the product of the cardiac output and the oxygen content of the blood.

The average healthy individual with a basal oxygen consumption has no more than 4 minutes supply of oxygen in the blood.

### 5.2 Pharmacokinetic properties

The uptake of oxygen by the blood in the lungs and discharge to the tissues is determined by the oxygen dissociation curve. The characteristic sigmoid shape ensures that, at tensions between 5kpa (40mm Hg) and 2kpa (15mm Hg) the oxygen carried in the blood from the lungs can readily be given up to the tissues.

The uptake from the lungs is rapid because blood flow through the capillaries, where the exchange takes place, occurs in about 0.5 seconds. The uptake of oxygen is favoured by the simultaneous loss of carbon dioxide which is then excreted in the expired air. Conversely, the entry of carbon dioxide into the blood from the tissues facilitates oxygen transfer to the cells.

At rest, mixed venous blood returning to the lungs contains 13-14ml of oxygen per 100ml, but with severe exercise, the oxygen content may fall to 3-4ml. In very active tissue, almost complete extraction occurs.

### 5.3 Preclinical safety data

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.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

None.

### 6.2 Incompatibilities

There are no known incompatibilities with oxygen.

### 6.3 Shelf life

3 years.

### 6.4 Special precautions for storage

- Medical Gas Cylinders should be stored in a secure area that is well ventilated, under cover, preferably inside, kept dry and clean and not subjected to extremes of heat or cold.
- Cylinders should not be stored near stocks of combustible materials or near sources of heat.
- The storage area should be kept clean and tidy, free from debris.
- Medical gas cylinders containing different gases should be segregated within the store and should be clearly identified.
- Full and empty cylinders should be stored separately.
- Medical gas cylinders should be stored separately from industrial cylinders and other types of non-medical cylinders.
- Full cylinders should be used in strict rotation so that cylinders with the earliest expiry dates are used first.
- Precautions should be taken to protect cylinders from theft.

### 6.5 Nature and contents of container

Medical Oxygen is a compressed gas supplied under pressure in a cylinder fitted with a valve to control the outflow of the gas.

The gas cylinder can be constructed from high-strength chromium-molybdenum steel, aluminium, aluminium liners with carbon wrap on either of the sides of the cylinder or all over.

The colour scheme for Medical Oxygen 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.

Medical oxygen cylinders are fitted with a valve. The valve can be a pin-index valve complying with BS EN 407 a bullnose valve complying with BS 341 or an integral pressure regulator valve that processes the cylinder pressure to a ultra low outlet pressure of 4.1 bar to ensure safe distribution. Integral pressure regulator valves are medical devices.

Cylinders fitted with pin-index or bullnose valves are used with a separate pressure regulator (medical device).

The gas cylinders have a variety of water capacities and are filled to 137, 200 or 300 bar. The following is a list of the nominal oxygen content in litres 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

Not all pack sizes may be marketed.

## 6.6 Special precautions for disposal and other handling

Use in accordance with the doctor's instruction.

### GENERAL

- Pipelines for medical gases should be controlled in accordance with the conditions set out in HTM 02.
- All personnel handling gas cylinders or being responsible for pipeline gas supplies should have adequate knowledge of:
  - o the properties of the gas,
  - o precautions to be taken,
  - o actions in the event of any emergency
  - o the correct operating procedures for their installation.
- If you own your own cylinders, you must be aware of and discharge your statutory obligations with regard to maintenance and testing.
- Ensure that when cylinders are collected the driver has been properly instructed in the method of handling cylinders and in dealing with any emergency.

### PREPARATION FOR USE

To prepare the cylinder for use, before placing near the patient:

- Ensure that the correct cylinder has been selected – check that the cylinder contains Medical Oxygen (Read the label on the cylinder).
- Ensure that the gas is within its expiry date (this is specified on a separate batch label on the shoulder of the cylinder).
- Remove the tamper evident seal (this is only applicable for the first use of the cylinder).
- Ensure that the cylinder is turned off.

### Cylinders used with a separate pressure regulator

- Check the gas pressure in the cylinder (read the label) and ensure that the cylinder is compatible with the equipment that it is being connected to. Only the appropriate regulator should be used for the particular gas concerned, correct for the specific product type and the cylinder pressure.
- Ensure that the connecting face of the pin-index valve, the manifold connection or the bullnose outlet of the valve and the regulator connection is clean and free from damage.
- Inspect any seal fitted to the regulator connector for signs of wear or feathering of the seal material or contamination with oil or grease. Replace the seal if there are any signs of wear, damage or contamination.
- Never use oil or grease or any lubricant to connect equipment to a cylinder valve.

- Connect the regulator. Tighten by hand using moderate force to make the connection. Do not use excessive force.
- Ensure that any equipment connected to the cylinder is turned off and any flow device fitted to the regulator is set to zero.
- Connect the appropriate size tubing to the tubing nipple outlet or the medical oxygen probe to the quick connect outlet (where fitted)
- Select the required flowrate (if appropriate) Turn the cylinder on slowly by opening the cylinder valve
- Check the connection for leaks.
  - o Should leaks occur, this would usually be evident by a hissing noise.
  - o If the leak occurs between the valve outlet and the regulator or the manifold connector, turn off the cylinder, depressurise and remove the connector. Replace the seal and reconnect the equipment following the instructions above.
  - o Sealing or joining compounds must never be used to cure a leak.
  - o Never use excessive force when connecting equipment to cylinders.
  - o If the leak persists, label the cylinder and arrange return of the cylinder to your supplier.

### **Cylinders with an integral pressure regulator valve**

- Ensure that the correct equipment is selected for connection to the cylinder valve.
- Never use oil or grease or any lubricant to connect equipment to a cylinder.
- Ensure the flow control (if fitted) is set to zero.
- Connect the appropriate sized tubing to the tubing nipple or the medical oxygen probe to the quick connect outlet on the cylinder (where fitted).
- Turn the cylinder on slowly, open the cylinder valve.
- Check the connection for leaks
  - o Should leaks occur, this would usually be evident by a hissing noise.
  - o If a leak is found, close the valve remove the connection, check and refit.
  - o Never use excessive force when connecting equipment to cylinders.
  - o If the leak persists, label the cylinder and arrange return of the cylinder to your supplier.

### **USE OF CYLINDERS**

- Medical gases must only be used for medicinal purposes.
- When cylinders are not in use they should be turned off, use moderate force to close the valve.
- Smoking and naked lights must not be allowed within the vicinity of cylinders or pipeline outlets.
- Cylinders should be handled with care, never knocked violently or allowed to fall over. Dropping a cylinder can damage the valve and may cause injury. If the cylinder is dropped or knocked in use it must be checked before further use.
- Never roll cylinders along the ground. Cylinders should only be moved with the appropriate size and type of trolley or using the correct handling techniques. Ensure that the cylinder is securely stowed when moving the cylinder.
- When in use, cylinders should be firmly secured to a suitable cylinder support. Take care as lightweight cylinders can be damaged by sharp objects such as securing screws.
- Do not place the cylinder on the patient's bed unless there is no suitable alternative for retaining the cylinder.
- Cylinders must not be repainted or have any marking obscured or labels removed.

### **AFTER USE**

- Turn off the supply of Medical Oxygen by closing the cylinder valve using moderate force only.
- Allow the equipment to vent any residual gas.
- If fitted turn the flow control to zero.
- Disconnect the equipment used to deliver the gas to the patient. Return empty cylinders to the empty cylinder store.
- Contact your supplier to arrange refill of the cylinder by Industrial Pressure Testing Ltd Unit H5 Marina Commercial Park Cork, Ireland.
- Cylinders that are no longer required should be returned to your supplier.

## **7 MARKETING AUTHORISATION HOLDER**

Industrial Pressure Testing Ltd  
Unit H4  
Marina Park Industrial Estate  
Cork  
Ireland

**8 MARKETING AUTHORISATION NUMBER**

PA1357/001/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 29<sup>th</sup> May 2015

**10 DATE OF REVISION OF THE TEXT**