# MEDICAL OXYGEN, 100% MEDICAL GAS COMPRESSED
PL 27970/0001

## UKPAR

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MEDICAL OXYGEN, 100% MEDICAL GAS COMPRESSED
PL 27970/0001

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency granted CSTS Limited, a
Marketing Authorisation for the medicinal product Medicinal Oxygen, 100% medicinal
gas, compressed (PL 27970/0001) on 13 February 2012. The product is a general sales list
medicine and is available under the supervision of a professional.

Medicinal Oxygen, 100% medical gas, compressed is colourless, odourless and tasteless. It
is supplied under pressure in a cylinder with a valve to control the flow of gas.

Medical Oxygen is used to treat the following conditions:
• Lung disease such as pulmonary thrombo-embolism (blockage of one of the arteries
  in the lung), pneumonia, fibrosing alveolitis (inflammation and scarring of the air-
sacs of the lungs) and pulmonary oedema (a disease affecting the heart)
• Breathing difficulties due to conditions such as chronic obstructive airways disease
  (COPD)
• Treatment of acute or severe asthma, sleep apnoea (a sleep disorder in which a
  person has irregular breathing at night and is excessively sleepy during the day),
  cluster headaches (severe one-sided headaches, over several weeks), shock (a
  dramatic reduction in blood flow that if left untreated, can lead to collapse, coma or
death)
• Resuscitation purposes
• When the oxygen carrying ability of the blood is reduced such as in carbon
  monoxide poisoning or severe anaemia
• When gas is trapped in body trapped in body spaces as in pneumothorax (air that is
  trapped next to a lung resting in collapse of the lung
• Air embolism or other gas disturbances such as decompression sickness (associated
  with diving)
• As a carrier gas or a diluent for anaesthetic gases or vapours.

This application is considered to be identical to the previously granted licence for
Medicinal Oxygen (PL 06183/0011) authorised to Air Products PLC since 30 June 1997 in
the UK.

No new or unexpected safety concerns arose from this application and it was, therefore,
judged that the benefits of taking Medicinal Oxygen, 100% medicinal gas, compressed
(PL 27970/0001) outweigh the risks; hence a Marketing Authorisation has been granted.
INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted CSTS Limited, a Marketing Authorisation for the medicinal product, Medicinal Oxygen, 100% medicinal gas, compressed (PL 27970/0001), on 13 February 2012. The product is a general sales list (GSL) medicine and used under the supervision of a professional.

This is a simple, abridged, ‘informed consent’ application submitted according to Article 10c of EC Directive 2001/83 (as amended), cross-referencing the Marketing Authorisation for Medicinal Oxygen (PL 06183/0011) authorised to Air Products PLC since 30 June 1997 in the UK. The reference product has been authorised in the EEA for over 10 years.

Experience of oxygen therapy has largely been derived from experience in man. Thus whilst there obviously have been laboratory studies, there are no formal ‘non-clinical’ observations to report.

No new data were submitted nor was it necessary for this simple application as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) has been generated for it.
1. INTRODUCTION
This is a simple, informed consent application for Medical Oxygen, 100% Medicinal Gas Compressed under Article 10c of Directive 2001/83/EC. The proposed Marketing Authorisation Holder is CSTS Limited, Warrington Business Park, Long Lane, Warrington, WA2 8TX, UK.

The application cross-refers to Medicinal Oxygen (PL 06183/0011) authorised to Air Products PLC since 30 June 1997. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 Name
The proposed name of the product is Medical Oxygen, 100% Medical Gas Compressed. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
The licensed product contains 100% compressed medicinal oxygen and is marketed in cylinders composed of either high strength chromium molybdenum steel alloy or high strength aluminium alloy. Both types of cylinders have base materials composed of steel or aluminium, fitted with valve. The aluminium cylinders are preferred for ambulatory uses and applications where portability is required due to the lightweight nature of the material used.

The approved shelf-life (36 months) with the storage instructions, “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” and is identical to the details registered for the cross-reference product. A list of the nominal oxygen content in litres of the cylinders at 15 C and 1013.2 mbar can be found in Section 6.5 of the SmPC.

2.3 Legal status
This product is a general sales list medicines (GSL) to be supplied by healthcare professionals only.

2.4 Marketing authorisation holder/Contact Persons/Company
The proposed Marketing Authorisation Holder is CSTS Limited, Warrington Business Park, Long Lane, Warrington, WA2 8TX, UK.
The Quality Person (QP) responsible for pharmacovigilance is stated and their curriculum
vita has been included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the
cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference
product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the
cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in-line with the details registered for the
cross-reference products.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the
cross-reference products.

2.10 TSE Compliance
There are no other excipients contained or used in the manufacturing process for the
proposed product. There is no material derived from animal or human origin or sourced
from genetically modified organisms. This is consistent with the cross-reference product.

3. EXPERT REPORT
A satisfactory quality overall summary has been prepared by an appropriately qualified
expert. The CV of the expert was provided.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The licenced product is a medical gas,
that consists solely of compressed oxygen conforming to the requirements of the
monograph of the European Pharmacopoeia and is identical to that of the cross-reference
product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The approved SmPC is consistent with the details registered for the cross-reference
product.

6. PATIENT INFORMATION LEAFLET (PIL)/CARTON
PIL
The PIL is satisfactory and in line with the approved SmPC and has been prepared in the
user-tested format.

To support the proposed patient leaflet, a bridging report has been provided for the
approved reference product, Medical Oxygen (PL 6183/0011) authorised to Air Products
PLC since 30 June 1997. The patient leaflet for the reference product met all criteria for
successful user testing. The proposed layout and content of the proposed patient leaflet is identical to that of the approved reference product. As a result, bridging justification is accepted for the proposed product without the need for further user testing.

Labelling
Mock-up of the labelling has been provided and are satisfactory. The approved artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements.

7. CONCLUSIONS
The data submitted with these applications are acceptable. A Marketing Authorisation was, therefore, granted.
NON-CLINICAL ASSESSMENT

This is a simple, abridged, ‘informed consent’ application made under Article 10c of EC Directive 2001/83 (as amended). This application is identical to the reference product, Medicinal Oxygen (PL 06183/0011) authorised to Air Products PLC on 30 June 1997 in the UK, therefore, no new non-clinical data has been supplied with this application and none are required. A non-clinical overview report has been written by a suitably qualified person and is satisfactory. The CV of the non-clinical expert has been supplied.

The marketing authorisation holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA). Oxygen is the second most abundant gas in the atmosphere. When medicinal oxygen is used in patients, it assists respiration but does not significantly increase over the norm the amount of oxygen lost from the atmosphere. Therefore the use of this product does not create an environmental risk.
CLINICAL ASSESSMENT

This is a simple, abridged, ‘informed consent’ application made under Article 10c of EC Directive 2001/83 (as amended), cross-referring to Medicinal Oxygen (PL 06183/0011) authorised by Air Products PLC since 30 June 1997 in the UK.

No new clinical data has been supplied with this application and none are required. A clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the clinical expert has been supplied.

The marketing authorisation holder (MAH) has provided adequate justification for not submitting a Risk Management Plan (RMP). As this application is identical to already authorised reference product, for which safety concerns requiring additional risk minimisation have not been identified, a risk minimisation system is not considered necessary. The reference products have been in use for many years and the safety profile of the active is well-established.

The MAH has provided a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that the MAH has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for these applications are consistent with those previously assessed for the cross-reference products and as such has been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY
This application is considered identical to the previously granted licence for Medicinal Oxygen (PL 06183/0011) authorised to Air Products PLC on 30 June 1997 in the UK.

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE
The approved SmPC, PIL and labelling are satisfactory, and consistent with those for the cross-reference product.

A bridging report has been provided for the approved reference product, (PL 06183/0011) Medicinal Oxygen (PL 06183/0011) authorised to Air Products PLC has been provided.. The patient leaflet for the reference products met all criteria for successful user testing. The proposed layout and content of the new patient leaflet is identical to that of the approved reference products. As a result, bridging justification is accepted for the proposed product without the need for further user testing.

Mock-ups of the labeling have been provided and are satisfactory. The labeling artwork complies with statutory requirements.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. The benefit; risk ratio is, therefore, considered to be positive.
**STEPS TAKEN FOR ASSESSMENT**

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<td>1</td>
<td>The MHRA received the marketing authorisation application on 2 March 2009.</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 21 September 2009.</td>
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<td>3</td>
<td>Following assessment of the application the MHRA requested further information relating to the quality dossier on 4 December 2009.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 18 November 2011.</td>
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<tr>
<td>5</td>
<td>The application was determined on 13 February 2012.</td>
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## STEPS TAKEN AFTER ASSESSMENT

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MEDICAL OXYGEN, 100% MEDICAL GAS COMPRESSED
PL 27970/0001

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Medical Oxygen, 100% medical gas, compressed (PL 27970/0001) is as follows:

1 NAME OF THE MEDICINAL PRODUCT
Medical Oxygen, 100% medicinal gas, compressed.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Consists solely of compressed oxygen conforming to the requirements of the monograph of the European Pharmacopoeia.

3 PHARMACEUTICAL FORM
Medicinal gas, compressed.

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 thromboembolism 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. 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 **Contraindications**

- High concentrations of oxygen are contra-indicated in chronic severe airways disease and premature neonates.
- 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.

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 **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 **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 infant exposure to excessive oxygen concentrations may be associated with the following conditions: retrolental fibroplasia, bronchopulmonary dysplasia, subependymal 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.

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 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
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.
Cylinder
The base materials of the cylinder are steel or aluminium, fitted with a valve.
Steel cylinder
This is of high strength chromium molybdenum steel alloy construction. The quality and heat treatment of this metal is such that the cylinder can withstand greater pressure than a cylinder of inferior steel of the same weight.
Aluminium cylinder
This is of high strength aluminium alloy construction. Cylinders of this material, due to its relatively lightweight, are preferred for ambulatory uses and applications where portability is required. There are two variations:

a. A cylinder entirely of aluminium alloy.

b. A cylinder of aluminium alloy over wrapped with windings of high strength fibre on the parallel section of the basic aluminium cylinder, the additional strength provided by the additional wrapping reduces the cylinder weight further. In either variation the oxygen product is only in contact with the aluminium alloy of the cylinder.

Cylinders are colour coded in accordance with BS 1319C.

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


6.6 Special precautions for 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
CSTS LIMITED
WARRINGTON BUSINESS PARK
LONG LANE
WARRINGTON
WA2 8TX
UNITED KINGDOM

8 MARKETING AUTHORISATION NUMBER(S)
PL 27970/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
13/02/2012

10 DATE OF REVISION OF THE TEXT
13/02/2012
Medical Oxygen, 100% Medical Gas Compressed
PL 27970/0001
PATIENT INFORMATION LEAFLET

Medical Oxygen, 100% medicinal gas, compressed - Patient Information Leaflet

Read all of this leaflet carefully because it contains important information for you. Keep this leaflet, you may need to read it again. Ask your pharmacist or doctor if you need more information.

In this Leaflet
1. What is Medical Oxygen and what it is used for Page 2 3. How to use Medical Oxygen
2. Before you use Medical Oxygen 4. Possible side effects
5. How to store Medical Oxygen
6. Further information

1. What is Medical Oxygen and what it is used for
Medical Oxygen is a breathed in (inhaled) gas. It is colourless, odourless and tasteless. It is supplied under pressure in a cylinder with a valve to control the flow of gas. A variety of cylinder sizes are available.

What Medical Oxygen is used for?
Medical Oxygen is used to increase the levels of oxygen in the body's tissues. It may be used in the following circumstances:

- at high concentrations when there is a reduced amount of oxygen being taken into the body through the lungs due to acute or severe asthma or lung diseases such as pulmonary thrombo-embolism (a blockage of one of the arteries in the lung), pneumonia, fibrosing alveolitis (inflammation and scarring of the air sacs of the lungs) and pulmonary oedema (a disease affecting the heart);
- in low concentrations when there are breathing difficulties due to conditions such as chronic obstructive airways disease (COPD) (a collection of lung diseases caused by damage to the lungs);
- in the treatment of acute and severe asthma, sleep apnoea (a sleep disorder in which a person has irregular breathing at night and is excessively sleepy during the day), diastolic headaches (attacks of severe, one-sided headaches over several weeks), shock (a dramatic reduction in blood flow that, if left untreated, can lead to collapse, coma and even death), and in other situations where broiled blood supply is poor;
- for resuscitation purposes by trained persons, where oxygen supply to the body is reduced due to medical emergency;
- when the oxygen carrying ability of the blood is reduced such as in carbon monoxide poisoning or severe anaemia (a condition which occurs when there is a reduced number of red blood cells or haemoglobin concentration);
- when gas is trapped in body spaces such as in pneumothorax (air that is trapped next to a lung resulting in collapse of the lungs) or an embolism or other gas disturbances such as decompression sickness (associated with diving);
- as a carrier gas or as a diluent for anaesthetic gases or vapours.

2. Before you use Medical Oxygen
Interactions with other medicines, medical conditions or diseases
Interactions with other medicines are unlikely when used as directed. However, it is important that you tell your doctor if you are taking, or have recently taken, any other medicine – even those not prescribed. Unless specially advised by your doctor to do so, do not use Medical Oxygen if:

- you are taking or have recently taken amiodarone (used to treat irregular heartbeat) or bleomycin (given as an injection or drip to treat some types of cancer);
- you have a Chronic Obstructive Pulmonary Disease (COPD) (a collection of lung diseases caused by damage to the lungs).

Take special care with Medical Oxygen
Care is needed in the handling and use of Medical Oxygen – You must follow your Doctor's instructions.

Fire Risks:
- do not smoke or allow those near you to smoke during treatment with Medical Oxygen; smoking during oxygen treatment has caused serious injuries and can prove fatal;
- do not allow naked flames in the area where you are using your Medical Oxygen, since even the smallest spark can cause violent giration of electrical equipment capable of sparking (including toys which may produce sparks) must not be used where you are using your Medical Oxygen.

Medical Risks:
- if oxygen is being used for a premature or newborn infant, they must receive a carefully monitored dose of oxygen. Giving too much oxygen can damage their sight;
- if you have a chronic obstructive airway disease you must receive a carefully monitored dose of oxygen;
- although Medical Oxygen is necessary for patients with lung disease due to poisons such as paraquat (a type of weedkiller), it may worsen the lung injury; the dose must be monitored carefully.

Takings Alcohol and Other Risks:
- a slowing down in your breathing caused by drinking alcohol may be made worse by the use of Medical Oxygen;
- do not breathe Medical Oxygen at pressures higher than atmospheric pressure.

Special Circumstances:
- Pregnancy
Medical Oxygen can be used if you are pregnant, however, seek medical advice before taking any medicine.

Premature/Newborn Babies
Medical oxygen for premature or newborn babies should only be taken under direction of a qualified medical person.

Breast-feeding
Medical Oxygen can be used if you are breast-feeding, however, seek medical advice before taking any medicine.

Driving and using machines
Non-continuous use of Medical Oxygen at atmospheric pressure will not affect your ability to drive or operate machinery. However, if you are using oxygen continuously you must be assessed by your doctor.
3. How to use Medical Oxygen

Medical Oxygen will be administered via inhalation and you will be given a facemask, mouthpiece or nasal cannula (prongs) to use, which are connected to the Medical Oxygen via a suitable medical device. The device must be operated in the manner described by the manufacturer. The amount of oxygen you will receive is controlled by the type of equipment you are supplied with and the flow rate. You must use the flow rate prescribed by your doctor and the equipment provided by your supplier.

The flow rate of oxygen used in your treatment will depend on the condition it is being used to treat. Your doctor will tell you how much oxygen you should use per day and how long your treatment with Medical Oxygen is likely to last.

Other systems used to administer oxygen include face tents, headboxes, cot hoods, a positive pressure mask or a supply to a tracheostomy. These systems will only be used to give you oxygen under the direct supervision of an attendant and suitably trained medical personnel.

Connections for hoses, valves etc. must be kept clean and dry. If necessary clean only with plain water. Do not use solvents. Use clean, lint free cloths for cleaning and drying off. Do not use oil or grease on any oxygen equipment.

Premature/Newborn Babies

Medical oxygen for premature or newborn babies should only be taken under direction of a qualified medical person.

If you use more Medical Oxygen than you should:

If you may have used more Medical Oxygen than you should, talk to a doctor or pharmacist as soon as possible. However, it is very unlikely that an overdose will occur.

Using 100% Medical Oxygen continuously for more than a day may produce chest pain and difficulties in breathing. Such a concentration is likely only to be achieved using specialised (hospital) equipment.

Using Medical Oxygen at pressure higher than atmospheric may lead to convulsions. This is only likely to occur in specialised circumstances when using decompression units, high altitude mountaineering or diving.

Withdrawal

There are no additional side effects from withdrawal of oxygen.

4. Possible side effects

Like all medicines Medical Oxygen can have side effects. The toxicity of Medical Oxygen depends upon both the pressure (concentration) of Medical Oxygen that is breathed in and the amount of time that it is used for. The higher the pressure that Medical Oxygen is breathed in, the shorter the time that it can be safely used for.

Side effects may include:
- giving too much oxygen in newborn and premature infants can damage their sight and may be associated with other damage (these conditions have more than one cause and can occur even in the absence of oxygen therapy)
- lung damage from prolonged giving too much oxygen - symptoms include shortness of breath, cough and chest discomfort
- central nervous system toxicity if Medical Oxygen is breathed in at pressures of twice atmospheric pressure or more as in hyperbaric oxygen therapy. This would normally only occur in hospital treatment. Symptoms could include nausea, mood changes, vertigo, twitching, convulsions and loss of consciousness

If you notice any side effects not mentioned in this leaflet please inform your doctor or pharmacist.

5. How to store Medical Oxygen

Check the date given on the batch label attached to the cylinder. Do Not Use Medical Oxygen after the expiry date given on the label.

Medical oxygen supplied in cylinders as a gas.
1. Keep Medical Oxygen out of the reach and sight of children.
2. Medical Oxygen must be stored securely in a well-ventilated place, under cover, clean and dry.
3. Medical Oxygen cylinders and must be stored at temperatures below 50°C and they should preferably be stored between 10°C and 30°C.
4. Medical Oxygen must be stored separately from other medical gases and non-medical gases and liquids.

6. Further information

The name of your medicine is Medical Oxygen, commonly named as Oxygen Inhalation Gas.
The active substance is Oxygen Ph. Eur., Minimum Purity 99.5% v/v.

Contents of the container:
Oxygen supplied as gas in cylinders; These contained compressed gas. The cylinder sizes quoted are the amount of oxygen provided by the cylinder, when it is used at normal atmospheric pressure
136, 200, 300, 400, 600 680, 1060, 1360, 2122, 2720, 4080, 4244, 6366, 6392 and 9973 litres.
Not all pack sizes may be marketed.

Further information on handling and using medical oxygen is available from CSTS Ltd., who deliver your oxygen or your patient information pack.

The Marketing Authorisation Holder and Manufacturer is:
CSTS Ltd., Warrington Business Park, Long Lane, Warrington, Cheshire, WA2 8TX.
Oxygen supplied as: Gas in cylinders Marketing Authorisation No. 279700001
Medical Oxygen Patient Information Leaflet Version 1 – Nov. 2011
MEDICAL OXYGEN, 100% MEDICINAL GAS, COMPRESSED
PL 27970/0001

LABELLING

MEDICAL OXYGEN, 100% MEDICINAL GAS, COMPRESSED
PL 27970/0001  Oxygen Ph Eur, EEC NO. 2319569  UK No. 1072
Medicinal gas, compressed.

STRONGLY SUPPORTS COMBUSTION

For inhalation use only. Read the leaflet before use
♦ Keep out of the reach and sight of children ♦ Keep in a well ventilated place
♦ Keep away from combustible material ♦ Use no oil or grease
♦ Keep the product away from extremes of heat and cold
♦ No smoking or naked flames in the vicinity of the cylinders
♦ Open and close valves slowly ♦ Close valve when not in use

PL Holder: CSTS Ltd
Warrington Business Park, Long Lane, Warrington, WA2 8TX, UK

In an emergency contact
CSTS Ltd
25 Jute Lane
Brimsdown
Enfield
Middlesex
EN3 7PF
Tel: 020 8805 5144
Fax: 020 8804 9740

LABEL ISSUE 11/2011

OXIDIZING AGENT

5.1

COMPRESSED GAS

2

VOLUME.................LITRES
PRESSURE..............AT 15°C

NOMINAL CONTENTS