

Medical air



Summary of Product Characteristics (SPC)

1. Name of the medicinal product	Medical Air.				
2. Qualitative and quantitative composition	<p>Medical Air cylinders are supplied to the following specification:</p> <table><tr><td>Oxygen Content</td><td>20.9% O₂ +/- 0.5%</td></tr><tr><td>Balance Nitrogen</td><td></td></tr></table> <p>The Medical Air specification complies with the current European Pharmacopoeia monograph (1238).</p>	Oxygen Content	20.9% O ₂ +/- 0.5%	Balance Nitrogen	
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Balance Nitrogen					
3. Pharmaceutical form	Medicinal gas, compressed.				
4. Clinical particulars					
4.1 Therapeutic indications	<p>Medical Air is used:</p> <ul style="list-style-type: none">• as a replacement for atmospheric air when the atmosphere is contaminated by noxious fumes, vapours or gases• as a power source for pneumatic equipment• in ventilators and incubators to provide uncontaminated and controlled air flows.				
4.2 Posology and method of administration	There is no distinction in the use of medical air between age groups. For breathing purposes, medical air is administered by various means, commonly by self-contained or compressed air line breathing apparatus.				
4.3 Contraindications	Medical air is contra-indicated when oxygen or other gaseous combinations are needed (airway obstruction, pneumonia and a myriad of cardio-respiratory conditions).				
4.4 Special warnings and precautions for use	Medical air should be never given if it contains less than 21% oxygen. Care is needed in the handling and use of medical air gas cylinders.				
4.5 Interaction with other medicinal products and other forms of interaction	Not applicable				
4.6 Pregnancy and lactation	Medical air does not adversely affect pregnancy and lactation.				
4.7 Effects on ability to drive and use machines	The use of medical air does not affect the ability to drive or use machinery				

4.8 Undesirable effects	<p>Not applicable.</p> <p>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:</p> <p>HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie</p>
4.9 Overdose	None applicable.
5. Pharmacological properties	Pharmacotherapeutic Group – Medical Gas ATC Code – VO3AN
5.1 Pharmacodynamic properties	<p>The characteristics of medical air are:</p> <ul style="list-style-type: none">• Odourless, colourless gas• Molecular weight 29.00• Boiling point -194°C (at 1 bar)• Density 1.225 kg/m³ (at 15°C). <p>Atmosphere air contains approximately 21% oxygen, 78% nitrogen and 1% argon with trace contents of other inert gases (xenon, neon, krypton). The nitrogen is absolutely inert, but the oxygen in air is essential to life for its cellular respiratory function.</p>
5.2 Pharmacokinetic properties	Under conditions of normal atmospheric pressure, the pharmacokinetic data on air, are essentially those of respiration, oxygen carriage and cellular metabolism and are inapplicable.
5.3 Preclinical safety data	Not applicable
6. Pharmaceutical particulars	
6.1 List of excipients	None
6.2 Incompatibilities	Medical Air is non-flammable but supports combustion. It is highly dangerous when in contact with oils, gases, tarry substances and many plastics due to the risk of spontaneous combustion with high pressure gases.
6.3 Shelf life	1 year.
6.4 Special precautions for storage	<p>Medical Air cylinders should be:</p> <ul style="list-style-type: none">• stored under cover, preferably inside, kept dry and clean, and not subjected to extremes of heat or cold and away from stocks of combustible material• stored separately from industrial and other non-medical cylinders• stored to maintain separation between full and empty cylinders• used in strict rotation so that cylinders with the earliest filling date are used first• stored separately from other medical cylinders within the store• F size cylinders and larger should be stored vertically. E size cylinders and smaller should be stored horizontally.

Warning notices prohibiting smoking and naked lights must be posted clearly in the cylinder storage area and the Emergency Services should be advised of the location of the cylinder store.

Care is needed when handling and using Medical Air cylinders.

6.5 Nature and contents of container

A summary of Medical Air cylinders, their size and construction, type of valve fitted and valve outlet pressure is detailed below:

Cylinder Size	Gas content (litres)	Cylinder Construction	Valve outlet	Valve Outlet Pressure bar(g)
AZ	170	Aluminium	Pin Index	137
E	680	Steel	Pin Index Thumbwheel Valve	137
F	1360	Steel	BS 341 No.3 Top Outlet MPR Valve	137
G	3400	Steel	BS 341 No.3 Top Outlet MPR Valve	137
J	6800	Steel	Side spindle Pin Index Valve	137

Cylinders

All cylinders used for the storage of Medical Air are manufactured from high tensile steel or aluminium.

The cylinders are designed with working pressure of at least 137 bar (g). The cylinders are coloured grey with a black and white quartered shoulder.

Cylinder valves

Medical Air cylinders are fitted with valves with outlet connections that conform to either ISO 407 (pin index) or BS 341 (5/8" BSP F) and are filled to 137 bar (g). These cylinder valves are constructed from high tensile brass with a steel spindle fitted with a Nylon 6.6 insert.

Cylinders are designed to be used with an additional pressure regulator.

Cylinders for use with MRI Scanners

The AZ Medical Air cylinder shell is manufactured from aluminium and the valve from high tensile brass and other non-magnetic components that are not attracted by high magnetic fields. The AZ Medical Air cylinder label carries the statement ‘Suitable for use with MRI scanners’ and is the only package that is specified as suitable for use within the vicinity of MRI scanners.

6.6 Instructions for Use/Handling

General

All personnel handling Medical Air cylinders should have adequate knowledge of:

- properties of the gas
- correct operating procedures for the cylinder
- precautions and actions to be taken in the event of an emergency.

Preparation for Use

To prepare the cylinder for use:

- remove the tamper evident seal and the valve outlet protection cap. Ensure the cap is retained so that it can be refitted after use
- ensure that an appropriate Medical Air regulator is selected for connection to the cylinder
- ensure the connecting face on the regulator is clean and the sealing washer fitted is in good condition
- connect the regulator, using moderate force only and connect the tubing to the regulator/flowmeter outlet. Only the appropriate regulator should be used for the particular gas concerned
- never use excessive force when connecting equipment to cylinders
- open the cylinder valve slowly and check for any leaks.

Leaks

Having connected the regulator or manifold yoke to the cylinder check the connections for leaks using the following procedure:

- Should leaks occur this will usually be evident by a hissing noise
- Should a leak occur between the valve outlet and the regulator or manifold yoke, depressurise and remove the fitting and fit an approved sealing washer
- Reconnect the fitting to the valve with moderate force only, fitting a replacement regulator or manifold tailpipe as required
- Sealing or jointing compounds must never be used to cure a leak
- If leak persists, label cylinder and return to BOC.

Use of cylinders

When Medical Air cylinders are in use ensure that they are:

- only used for medicinal purposes
- turned off, when not in use, using only moderate force to close the valve
- only moved with the appropriate size and type of trolley or handling device
- handled with care and not knocked violently or allowed to fall
- firmly secured to a suitable cylinder support when in use
- not used in the vicinity of persons smoking or near naked lights.

Use of cylinders with MRI scanners

When Medical Air cylinders are required to be used in the vicinity of MRI scanners, they should be tested with the appropriate equipment to ensure that they have no components that are attracted by high magnetic fields. It is recommended that only AZ Medical Air cylinders are used in the vicinity of MRI scanners.

After use

When the Medical Air cylinders are empty ensure that the:

- cylinder valve is closed using moderate force only and the pressure in the regulator or tailpipe released
- valve outlet cap, where fitted, is replaced
- empty cylinders are immediately returned to an empty cylinder store for return to BOC.

7. Marketing authorisation holder

BOC Gases Ireland Limited
J F Kennedy Drive
Bluebell
Dublin 12

8. Marketing authorisation number(s)

PA 208/9/1

9. Date of first authorisation/renewal of the authorisation

Date of first authorisation: 27/09/1985.
Date of last renewal: 01/04/2010.

10. Date of revision of the text

November 2015.

11. Dosimetry (if applicable)

Not applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)

Not applicable.

Additional Safety Information

1. Contact information BOC telephone number to be used in the event of an emergency
ROI 1890 355 255

2. Hazards Classification labelling and packaging regulations



Warning.
Contains gas under pressure; may explode if heated (H280).
Protect from sunlight: store in a well-ventilated place. (P410 + P403).

Dangerous preperations directive



Keep out of the reach of children (S2).

Additional safety statements

- No smoking or naked flames near medical gas cylinders
- Use no oil or grease
- Keep away from extremes of heat and combustible material
- Store cylinders under cover in a clean, dry and well ventilated area.

Medical air is supplied as a compressed gas in a high pressure cylinder. Cylinders may explode if subjected to extremely high temperatures (if involved in a fire).

3. Fire fighting measures If medical air cylinders are involved in a fire:

- if it is safe to move the cylinders,
 - close cylinder valve to stop flow of product
 - move cylinders away from source of heat
- if it is not safe to move the cylinders,
 - cool with water from a protected position.

All types of fire extinguishers may be used when dealing with a fire involving medical air cylinders. No special protective equipment for fire fighters is required. There are no hazardous combustion products released from the gas.

4. Accidental release measures If a large volume of medical air is released, if it is safe to do so, you should close the cylinder valve.

5. Exposure controls None.

6. Disposal considerations It is recommended that medical air cylinders should not be vented after use - they should be returned to BOC with any residual gas where they will be vented before refilling in a safe environment.

If, for safety reasons, a cylinder is required to be vented after use, the gas should be vented to atmosphere in a well ventilated area.

Contact BOC if further guidance on venting cylinders is required.

7. Transport of cylinders When medical air cylinders are required to be transported, ensure that the cylinders are:

- located in a compartment separated from the driver
- adequately restrained
- not leaking and have their valves closed.

The vehicle must be adequately ventilated. Ensure the driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.

It is advisable to provide the driver with written instructions that detail the actions to be taken in the event of an accident or emergency.

Cylinders should be removed from the vehicle as soon as possible.

7. Transport information

UN number	UN1002
Proper Shipping Name	Air, compressed
Material	Class 2
Labels	2.2
Hazard identification number	20
Emergency Action Code	2T
Tunnel Restriction code	E
Transport category	3

BOC Healthcare

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