

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Medical Air

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Medical Air cylinders are supplied to the following specification:

Oxygen $O_2 \pm 0.5\%$

Nitrogen

The Medical Air specification complies with the current European Pharmacopoeia monograph (1238).

3 PHARMACEUTICAL FORM

Medicinal gas, compressed.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Medical Air is used:

- 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 never be 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 Fertility, 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

Not applicable.

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; e-mail: medsafety@hpra.ie.

4.9 Overdose

None applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Medical Gas
ATC Code: V03AN

The characteristics of medical air are:

- Odourless, colourless gas.
- Molecular weight 29.00
- Boiling point -194°C (at 1 bar)
- Density 1.225kg/m³ (at 15°C)

Atmosphere air contains approximately 12% 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.

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

Medical Air cylinders should be:

- 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	160	Aluminium	Pin Index	137
E	640	Steel	Pin Index Thumbwheel valve	137
F	1280	Steel	BS 341 No.3 Top Outlet MPR Valve	
G	3200	Steel	BS 341 No.3 Top Outlet MPR Valve	137
J	6400	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 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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 cylinder 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

PA0208/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 September 1985

Date of last renewal: 01 April 2010

10 DATE OF REVISION OF THE TEXT

November 2015

11 DOSIMETRY

Not applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable