BOC
A Member of The Linde Group

Medical air.

Essential safety information.

BOC: Living healthcare

Medical air SPC

1. Name of the medicinal product

Medical air.

2. Qualitative and quantitative composition

Medical air specification.

Medical air cylinders are supplied to the following specification:

oxygen content	20.9% O2 ± 0.5%
nitrogen	balance.

The medical air cylinder specification complies with the 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
- in anaesthesia as a carrier gas for volatile anaesthetic agents
- 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

For breathing purposes medical air is administered by various means, commonly by self contained or compressed air line breathing apparatus.

In anaesthesia, medical air is administered via a cylinder and valve assembly through a face mask or endotracheal tube.

4.3 Contraindications

Medical air is contraindicated where oxygen or other gaseous combinations would be indicated (airways obstruction, pneumonia, and a myriad of cardio-respiratory conditions).

4.4 Special warnings and precautions for use

Medical air should never be administered to a patient if, when it is mixed with other gases, the oxygen content is less than 21%.

Care is needed in the handling and use of medical air cylinders.

4.5 Interaction with other medicinal products and other forms of interaction

None 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

None 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 The Yellow Card System www.mhra.gov.uk/yellowcard

4.9 Overdose

None applicable.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The characteristics of medical air are:

- odourless, colourless gas
- molecular weight 29.00
- sublimation point -194°C (at 1bar(g))
- density 1.225kg/m^3 (at 15°C).

Atmospheric 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 an absolute necessity for life for its cellular respiratory function.

5.2 Pharmacokinetic properties

Under conditions of normal atmospheric pressure, the pharmacokinetic data on medical air are essentially those of respiration, oxygen carriage and cellular metabolism and are inapplicable.

5.3 Preclinical safety data

None stated.

6. Pharmaceutical particulars

6.1 List of excipients

None.

6.2 Incompatibilities

Medical air is non-flammable but supports combustion.

6.3 Shelf life

36 months.

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.

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6.5 Nature and contents of container

Medical air cylinder and valve details

Medical air is supplied as a compressed medical gas in high pressure gas cylinders. All cylinders used for the storage of medical air are manufactured from high tensile steel. The E, F, G and J size cylinders are designed with working pressure of at least 137bar(g) and the T4 and T7 size cylinders are designed for a maximum working pressure of 230bar(g).

Medical air cylinders are supplied with two main types of cylinder valves, dependant upon the cylinder filling pressure and the type of application.

Conventional cylinder valves are fitted to all cylinders which are designed to be used with a pressure regulator. All of these 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 137bar(g).

Other high pressure cylinders are fitted with valves that have an integral pressure regulator, with an outlet pressure of 4bar(g) or 7bar(g) dependant on their intended use. These regulated valves are fitted with an ISO 5145 product specific filling connection and a product specific BS 5682 Schrader outlet connection.

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 type outlet connections	Nominal valve outlet pressure bar (g)
AZ	170	Aluminium	Pin Index	137
E	680	Steel	Pin Index	137
F	1,360	Steel	Thumbwheel valve BS 341 No.3	137
G	3,400	Steel	Top outlet MPR valve BS 341 No.3 Top	137
J	6,800	Steel	Outlet MPR valve Side spindle pin	137
T4	4,600	Steel	Index valve Variable demand (0-300 litres/min) Integral regulated Valve with ISO 5145 product specific filling port and BS Schrader outlet (air 4bar(g))	4
T7	4,600	Steel	Variable demand (0-300 litres/min) Integral regulated valve with ISO 5145 product specific filling port and BS Schrader outlet (air 7bar(g))	7

The basic specification for the cylinder valves used in medical air cylinders are:

Valve component	Specification
Valve body	High tensile brass
Spindle	Steel
Spindle tip	Nylon 6.6
Valve outlet	5/8" BSP (F) side outlet
Valve operation	Handwheel
'O' rings (T4/T7 only)	Sintered bronze

6.6 Special precautions for disposal and other handling

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

Cylinders used with a pressure regulator. Sizes E, F, G, J.

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
- do not remove and discard any batch labels fitted to the cylinder
- 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
- open the cylinder valve slowly and check for any leaks
- The cylinder valves and any associated equipment is not lubricated and kept free from oil and grease.

Cylinders with an integral regulated valve. Sizes T4 and T7.

To prepare the cylinder for use:

- check the cylinder contents gauge on the cylinder valve to ensure that there is sufficient gas contents in the cylinder
- remove the tamper evident seal and cover fitted over the valve outlets ensure that the correct equipment is selected for connection to the cylinder
- connect the air Schrader probe to the Schrader outlet
- open the cylinder valve slowly and check for any leaks
- the cylinder valves and any associated equipment is not lubricated and kept free from oil and grease.

Leaks

Cylinders used with a pressure regulator. Sizes E, F, G, J.

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.

Cylinders with an integral regulated valve. Sizes T4 and T7.

Check the connection for leaks using the following procedure:

- should leaks occur this will usually be evident by a hissing noise
- close valve, remove connection, check and refit
- never use excessive force when connecting equipment to cylinders
- 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 allowed to have any markings, labels or batch labels obscured or removed
- not used in the vicinity of persons smoking or near naked lights.

After use

When the medical air cylinders are empty ensure that the:

- cylinder valves 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 storage area for return to BOC.

7. Marketing authorisation holder

BOC Ltd
The Priestley Centre
10 Priestley Road
The Surrey Research Park
GUILDFORD
Surrey, GU2 7XY

8. Marketing authorisation number(s)

PL 00735/5002R.

9. Date of first authorisation/renewal of the authorisation

Date first granted: 01/09/1972.
Date of renewal: 21/07/1992.

10. Date of revision of the text

25/05/2016

11. Dosimetry (if applicable)

Not applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)

Not applicable.

Notes

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Additional Safety Information

1. Contact information

BOC telephone number to be used in the event of an emergency
UK 0800 111 333

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 Preparations 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 the 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.

8. 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

Notes.

Notes.

BOC Healthcare
Customer Service Centre, Priestley Road, Worsley, Manchester M28 2UT
Tel 0800 111 333, Fax 0800 111 555, bochealthcare-uk@boc.com, www.bochealthcare.co.uk

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