

Compressed medical oxygen.

Essential safety information.



Summary of Product Characteristics (SPC)

4.3 Contraindications

There are no absolute contraindications to the use of compressed medical oxygen.

4.4 Special warnings and precautions for use

- Special care is needed when using compressed medical oxygen in neonates where retrolenticular fibrosis may occur.
- Use with caution in elderly patients with chronic obstructive pulmonary disease (COPD) and in patients with a risk of carbon dioxide retention.
- Use with caution in patients with a risk of hyperbaric chamber infections and acute respiratory infections.

Careful monitoring of oxygen concentrations is necessary when using compressed medical oxygen in patients with reduced oxygen concentrations.

In patients with reduced oxygen concentrations, the use of compressed medical oxygen may cause, or exacerbate, hypoxia which in extreme cases can lead to death.

Where the patient has a history of asthma, compressed medical oxygen containing more than 1% of nitrous oxide should not be used.

Compressed medical oxygen should be used near sources of ignition and away from heat near the patient. Do not use compressed medical oxygen if the cylinder is retaining the cylinder pressure.

Smoking should be prohibited when using compressed medical oxygen.

Under no circumstances should compressed medical oxygen be used in an oxygen cylinder or other container.

Where moisturising compressed medical oxygen should not be used.

Check that hands are clean before use.

Where alcohol gels are used, ensure they are fully evaporated before use.

The use of higher levels of oxygen should be administered with caution. Bleomycin should be administered with caution.

4.5 Interaction with other medicinal products and other forms of interaction

1. Name of the medicinal product
Compressed medical oxygen.

2. Qualitative and quantitative composition
Compressed medical oxygen cylinders are supplied to the following specification:
Compressed medical oxygen purity 99.5%(min)

The compressed medical oxygen cylinder specification complies with the current European Pharmacopoeia monograph (0417).

3. Pharmaceutical form
Medicinal gas, compressed.

4. Clinical particulars

4.1 Therapeutic indications
Medical Oxygen is widely used in clinical practice to:

- provide a basis for most modern anaesthetic techniques including pre and postoperative management.
- restore the tissue oxygen tension towards normal by improving oxygen availability in a wide range of conditions such as:
 - cyanosis of recent origin as a result of cardio-pulmonary disease
 - surgical trauma, chest wounds and rib fracture
 - shock, severe haemorrhage and coronary occlusion
 - carbon monoxide poisoning
 - hyperpyrexia
 - major trauma, i.e. road traffic accidents and gunshot wounds
 - in the management of sudden cardiac and respiratory arrest, whether drug induced or traumatic

6.6 Special precautions for disposal and other handling

All personnel handling compressed medical oxygen 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 AZ, D, E, F, AF, G, J and W

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

- 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 the batch label fitted to the cylinder is not removed or discarded
- ensure that an appropriate compressed medical oxygen regulator or manifold tailpipe 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 or tailpipe, using moderate force only and where appropriate 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.

Cylinders with an integral regulated valve

Sizes ZA, ZD, CD, DD, DF, ZH, HX, and ZX

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

- 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 the batch label fitted to the cylinder is not removed or discarded
- ensure that the correct equipment is selected for connection to the cylinder

Connect as appropriate either:

- the appropriate sized tubing to the fir tree outlet
- the medical oxygen Schrader probe to the Schrader outlet (where fitted)
- open the cylinder valve slowly and check for any leaks

Size IQX

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

- check the cylinder contents indicator on the electronic display to ensure that there is sufficient gas contents in the cylinder
- remove the tamper evident seal and cover fitted over the valve outlets
- ensure the batch label fitted to the cylinder is not removed or discarded

- sealing or jointing
- never use excessively
- if leak persists, lab

Cylinders with an inte

Sizes ZA, ZD, CD, DD, C

Check the connection

- should leaks occur
- close valve, remov
- never use excessiv
- if leak persists, lab

Use of cylinders

When compressed me

- only used for medic
- turned off, when n
- only moved with th
- handled with care
- used with an appro
- patient. Do not pla
- the cylinder
- not allowed to hav
- not used in the vic

After use

Cylinders used with a

Sizes AZ, D, E, F, AF, G,

When the compressed

- cylinder valve is cl
- valve outlet cap, w

Cylinders with an inte

Sizes ZA, ZD, CD, DD, C

When the compressed

- cylinder valve is cl
- valve is allowed to
- equipment is disco
- valve outlet cap, w

7. Marketing authorisation holder

BOC Limited
The Priestley Centre
10 Priestley Road
The Surrey Research Park
Guildford
Surrey, GU2 7XY

8. Marketing authorisation number(s)

PL 00735/5000R

9. Date of first authorisation/renewal of the authorisation

Date first granted 01/09/1972
Date of renewal 21/07/1997

10. Date of revision of the text

08/05/2019

11. Dosimetry (if applicable)

Not applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)

Not applicable.

Supply classification

1. Supply classification status

General Sales List.

Additional Safety Information

4. Accidental release measures

- If a large volume of medical gas is released from the cylinder:
- close the cylinder valve
 - where possible, isolate the cylinder
 - if release continues, evacuate the area
 - adequately ventilate the area

Self-contained breathing apparatus should be used.

5. Exposure controls

When using medical oxygen, ensure that the oxygen cylinder is not overfilled. Oxygen should be vented to atmosphere.

6. Disposal considerations

It is recommended that the cylinder be returned to BOC, with any residue of gas.

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



Danger:

May cause or intensify fire; oxidiser (H270).

Contains gas under pressure; may explode if heated (H280).

Keep/Store away from clothing, hydrocarbons and combustible materials (P220).

Keep reduction valves free from grease and oil (P244).

In case of fire: stop leak if safe to do so (P370 + P376).

Protect from sunlight: store in a well-ventilated place P410 + P403).

Dangerous Preparations Directive



Contact with combustible material may cause fire (R8).

Keep out of the reach of children (S2).

Keep away from combustible material (S17).

Label statements

- Contact with combustible material may cause fire
- No smoking or naked flames near medical oxygen 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 oxygen is supplied as a compressed gas in a high pressure cylinder.

7. Transport of cylinders

When medical oxygen cylinders are transported, they should be located in a compartment that is adequately restrained and not leaking and handled in accordance with the relevant regulations.

The vehicle must be a suitable type and must be a suitable size and must be a suitable type and must be a suitable size and must be a suitable type.

It is advisable to provide a fire extinguisher in the vehicle in the event of an accident or emergency.

8. Use of cylinders in transit – advice to patient/carer

- If you need to use medical oxygen in transit, you should:
- prohibit smoking in the vehicle
 - only carry the minimum amount of oxygen for the journey/activity
 - ensure all cylinders are properly secured
 - keep cylinder valves closed
 - avoid using the cylinder in a confined space
 - set the ventilation system to recirculate air

Notes

Notes

BOC Healthcare

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