

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Synthetic Medical Air
21% Oxygen v/v medicinal gas, compressed

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	Percentage
Oxygen	Nominal content 21 %

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Medicinal Gas, Compressed

Synthetic Medical Air 21% v/v, medicinal gas, compressed is a colourless, odourless gas packaged into cylinders which have either a white or grey body and black and white quartered shoulder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Synthetic 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 Synthetic Medical Air is administered by various means, commonly by self contained or compressed air line breathing apparatus.

In anaesthesia, Synthetic Medical Air is administered via a cylinder and valve assembly through a face mask or endotracheal tube.

4.3 Contraindications

There are no absolute contraindications

4.4 Special warnings and precautions for use

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

Synthetic Medical Air is non flammable but strongly supports combustion and should not be used near sources of ignition.

Synthetic Medical Air Cylinders should be set up and tested before placing near the patient. Do not place the cylinder on the patient's bed unless there is no suitable alternative for retaining the cylinder.

Smoking should be prohibited when using Synthetic Medical Air.

Under no circumstances should oils or grease be used to lubricate any part of the Synthetic Medical Air cylinder or the associated equipment used to deliver the gas to the patient.

Where moisturising creams are required for use with a facemask or in nasal passages, oil based creams should not be used.

Check that hands are clean and free from any oils or grease.

Where alcohol gels are used to control microbiological cross-contamination ensure that all alcohol has evaporated before handling Synthetic Medical Air cylinders or equipment.

4.5 Interaction with other medicinal products and other forms of interaction

There are no reports of interaction with synthetic medical air

4.6 Fertility, pregnancy and lactation

Pregnancy

Synthetic Medical Air can be used during pregnancy

Breastfeeding

Synthetic Medical Air can be used during lactation

Fertility

Synthetic Medical Air has no known negative effects on fertility

4.7 Effects on ability to drive and use machines

The use of Synthetic 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

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other therapeutic products-medicinal gases

ATC code: V03AN05

The characteristics of medical air are:

Odourless, colourless gas

Molecular weight 29

Boiling point -194°C (at 1 bar (g))

Density 1.225 kg/m³ (at 15°C)

Oxygen is vital to life and must be continuously supplied to all tissues in order to maintain the cells' energy production. Ambient air contains approximately 21% oxygen and 79% nitrogen. Synthetic air contains 21% oxygen, and 79% nitrogen and is mainly used because of its oxygen content.

The final target for the oxygen is the mitochondria in the individual cells, where oxygen is consumed in an enzymatic chain reaction, forming energy. Oxygen (in the form of reactive oxygen species) is also essential to a number of immunological defence mechanisms.

Nitrogen gas is in equilibration in the total lung volume and has no pharmacological effects in the body. Nitrogen may be considered as inert.

5.2 Pharmacokinetic properties

Synthetic air contains approximately 21% oxygen, which is almost identical to the concentration of oxygen in ambient air. It is administered via the airways to the lung. In the pulmonary alveoli, gas exchange, down a partial pressure gradient, takes place from the inspired air/gas mixture to the capillary blood.

The oxygen is transported by the systemic circulation mainly bound to haemoglobin to the capillary beds in the different tissues in the body. Only a very small portion is free, dissolved in plasma. During passage through the tissues, a partial pressure-dependent transport of the oxygen to the individual cells takes place. Oxygen that is absorbed in the body is excreted almost entirely as carbon dioxide formed in the intermediary metabolism.

Nitrogen is not absorbed, and is exhaled without having undergone any conversion/metabolism.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Nitrogen

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Synthetic 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 expiry 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 Synthetic Medical Air cylinders.

6.5 Nature and contents of container

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

Size	Gas Content (litres)	Water Capacity (Litres)	Material of Construction	Valve Connection		Nominal Valve Outlet Pressure Bar(g)
				Valve Type	Valve Connection Standard / Specification	
E	640	4.7	Steel	Valve Connection	Pin Index	137
				Valve Type	Non MPR/RPV Non-regulated	
				Valve Connection Standard / Specification	Outlet: ISO 407	
F	1280	10	Steel	Valve Connection	5/8" Bullnose / Top Outlet	137
				Valve Type	MPR/RPV Non-regulated	
				Valve Connection Standard / Specification	Outlet: BS 341 No 3	
HX	2150	10	Steel	Valve Type	Valve Integral with Pressure Regulator (VIPR) MPR/RPV type valve.	4
				Valve Connection Standard /	Filling Port: ISO 5145	

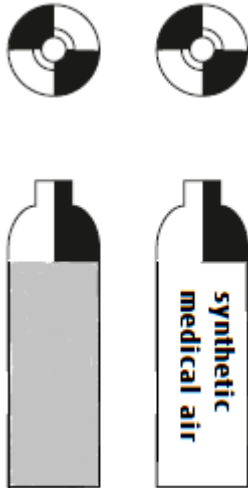
				Specification Flow Requirements	Outlet (1): 6mm fir tree EN 13544-2 Flowrate 1 - 15 litres/min	
					Outlet (2): BS 5682 Flowrate 40 litres/min (max)	
G	3200	23	Steel	Valve Connection	5/8" Bullnose / Top Outlet	137
				Valve Type	MPR/RPV Non-regulated	
				Valve Connection Standard / Specification	Outlet: BS 341 No 3	
J	6400	46.5	Steel	Valve Connection	Pin Index (Side Spindle)	137
				Valve Type	Non MPR/RPV Non-regulated	
				Valve Connection Standard / Specification	Outlet: ISO 407	
WJ	96000	697.5	Steel	Valve Connection	3/4" Bullnose / Top Outlet	137
				Valve Type	MPR/RPV Non-regulated	
				Valve Connection Standard / Specification	Outlet: Non-standard	

Cylinders

All cylinders used for the storage of Synthetic Medical Air are manufactured from steel.

The E, F, G, J and WJ size cylinders/packages are designed with working pressure of 137 bar(g)

The HX size cylinders are designed with a maximum working pressure of 230 bar (g).



The colour coding of the shoulders of Synthetic Medical Air cylinders is quartered white and black.

The cylinder bodies of the E, F, G, J and WJ packages are painted grey.

The cylinder body of the HX package is painted white. These cylinders also carry the name of the product on the body of the cylinder.

Cylinder Valves

Conventional cylinder valves are fitted to E, F, G and J cylinders which are designed to be used with a pressure regulator.

The E and the J size cylinders are fitted with a valve that has a Medical Air specific pin index outlet.

The F and G size cylinders are fitted with a BS341 No. 3 top outlet valve with a 5/8" BSP(F) thread. These cylinder valves are fitted with a residual pressure device in order to retain a nominal pressure after use to prevent the ingress of atmospheric contaminants should the valve be left open after use.

The WJ manifolded cylinder package is fitted with 15 J size cylinders that are interconnected via a high pressure manifold and tailpipes to provide a cylinder package with a higher capacity. The outlet connection for the WJ manifold cylinder pallet has a unique 3/4" BSP(F) threaded outlet as a gas specific outlet to prevent other manifolded cylinder pallets being connected to the Synthetic Medical Air system.

HX cylinders are fitted with valves that have an integral pressure regulator, with an outlet pressure of 4 bar(g). These regulated valves are fitted with an ISO 5145 product specific filling connection and a product specific BS 5682 Schrader outlet connection and a standard 6mm fir tree outlet. Integral cylinder valves are constructed from high tensile brass with a steel spindle fitted with a Nylon 6.6 insert.

All cylinder valves are constructed from high tensile brass and the main shut off valve spindle is manufactured from Monel and fitted with a Nylon 6.6 soft seat.

The internal valve components in the valves are made from oxygen compatible materials, designed to not produce poisonous fumes if the cylinder is subjected to high temperatures, causing ignition of any of the valve components.

6.6 Special precautions for disposal and other handling

All personnel handling Synthetic 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.

Cylinders used with a pressure regulator

Sizes E, F, G, J and WJ

To prepare the cylinder/manifold for use, before use and/or placing near the patient:

- check the expiry date on the batch label to ensure that the cylinder is in date. Ensure the batch label fitted to the cylinder/manifold cylinder pallet is not removed or discarded
- 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 regulator is selected for connection to the cylinder/manifold.
- 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 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/master valve slowly and check for any leaks.

Cylinders with an integral regulated valve

Size HX

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 to provide the therapy for the patient.
- 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 by fitting either:

- the appropriate sized tubing to the fir tree outlet or
- the Medical Air Schrader probe to the Schrader outlet (where fitted)

- open the cylinder valve slowly and check for any leaks

Leaks

Cylinders used with a pressure regulator

Sizes E, F, G, J and WJ

Having connected the regulator to the cylinder/manifold cylinder pallet outlet, check the connections for leaks using the following procedure:

- should leaks occur this will usually be evident by a hissing noise.
- if a leak occurs between the valve outlet and the regulator depressurise and remove the connector and fit an approved replacement sealing washer. Reconnect the connector to the valve with moderate force only. If necessary fit a replacement regulator as required.
- never use sealing or jointing compounds to cure a leak or use excessive force when connecting equipment to cylinders.
- if a leak persists, label cylinder/manifold cylinder pallet and return to BOC

Cylinders with an integral regulated valve

Size HX

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 a leak persists, label cylinder and return to BOC

Use of Cylinders

When Synthetic 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.
- used with an appropriately designed cylinder support to hold the cylinder whilst in use adjacent to the patient. Do not place the cylinder on the patient's bed unless there is no suitable alternative for retaining the cylinder
- 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

Cylinders used with a pressure regulator

Sizes E, F, G, J and WJ

When the Synthetic Medical Air cylinder/package are empty ensure that the:

- cylinder valve /manifold cylinder pallet master valve is closed using moderate force only and the pressure in the regulator released.
- valve outlet cap, where fitted, is replaced

Cylinders with an integral regulated valve

Size HX

When the Synthetic Medical Air cylinders are turned off or empty ensure that the:

- cylinder valve is closed slowly using moderate force only
- valve is allowed to vent before turning the flow selector to zero
- equipment is disconnected
- valve outlet cap, where fitted, is replaced

Empty cylinders must be returned immediately to an empty cylinder storage area for return to BOC.

7 MARKETING AUTHORISATION HOLDER

BOC Ltd
Forge
43 Church Street West,
Woking,
Surrey,
GU21 6HT,
United Kingdom

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: 16/07/2005

10 DATE OF REVISION OF THE TEXT

20/10/2022