6.3 Shelf life 12 months**.**

6.4 Special precautions for storage
Medical air cylinders should be:

- Store in the shade. 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 to maintain separation between full and empty cylinders.
- Used in strict rotation so that cylinders with the earliest filling date are used first.
- Care is needed when handling and using medical air cylinders.
-

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 (made of steel or aluminum).
Medical air cylinders are supplied with brass cylinder valves.

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.

7. Manufacturer, License Holder and Distributor
Oxygen and Argon Works Ltd
South Industrial Zone, Havatzelet HaChof St., Caesarea

8. **License number** 147 58 33524 00

פורמט עלון זה נקבע ע"י משרד הבריאות ותוכנו נבדק ואושר על ידו
ב 3.2012

מפעלי חמצן וארגון בע"מ

(ייצור ומילוי גזים)

קיסריה, פארק התעשייה הדרומי. ת"ד 3159, מיקוד 3079532

טל. 8792* פקס. 04-6231535

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This leaflet format has been determined by the Ministry of Health and the content has been checked and approved in 3.2012

Medical Gas Data Sheet (MGDS)
Air Medical Gas
Summary of Product Characteristics (SPC)

אנו מאשרים בזאת שהמוצר המסופק בגליל זה עומד במפרטי
"מפעלי חמצן וארגון בע"מ"
לסוג הגז ולדרגת הניקיון הרשומים על התג.
(ניתן לקבל את מפרט הגז ע"י פניה למחלקת הבטחת איכות)

TOF – 410
Ver. B
07.10.2019

J148-510

1. Name of the medicinal product
Air Medical Gas
2. Qualitative and quantitative composition
Medical air specification.
Medical air cylinders are supplied to the following specification:
oxygen content 20.9% O_2 ± 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
Gas for Inhalation
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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form /https://sideeffects.health.gov.il**4.9 Overdose**
None applicable.
5. Pharmacological properties
5.1 Pharmacodynamic properties
The characteristics of medical air are:
Odorless, colorless gas
Molecular weight 29.00
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.