

Physician Prescribing Information

# Air, Synthetic Medicinal

## Summary of Product Characteristics (SPC)

### **1. Name of the medicinal product**

Air, Synthetic Medicinal

### **2. Qualitative and quantitative composition**

Medical air specification.

oxygen content: 21.0%- 22.5% v/v

The medical air cylinder specification complies with the European Pharmacopoeia monograph (1684).

### **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 authorization 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

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffe>  
[ctMedic@moh.gov.il](mailto:ctMedic@moh.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.

#### **6.3 Shelf life**

The expiry date of the product is indicated on the packaging materials

#### **6.4 Special precautions for storage**

Medical air cylinders should be:

- Store in a well ventilated place Below 52<sup>0</sup>C.

#### **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.

#### **ADMINISTRATIVE DATA**

##### **7. MARKETING AUTHORISATION HOLDER**

Maxima Air Separation Center LTD

10 Haogen st. P.O.B.4124, Ashdod 7714101 . Israel

##### **8. MARKETING AUTHORISATION NUMBER**

**161-29-35370-00**