SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Medicinsk luft Nippon Gases Scandinavia 100 %, medicinal gas, compressed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Medicinal air 100 % at a pressure of 200 bar (15 °C).

3. PHARMACEUTICAL FORM

Medicinal gas, compressed
Colourless, odourless gas

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Medicinal air is indicated as a replacement for normal environmental/room air whenever it is required, e.g.:

- In cases of respirator treatment or in connection with anaesthesia as a part of the fresh gas flow in order to give a gas mixture with the desired oxygen content (FiO2)
- As propellant in nebulisation treatment
- As pure air in the care of immunosuppressed patients such as in cases of organ/cell transplantation or extensive burn wounds.

4.2 Posology and method of administration

Dosage
The purpose of using medicinal air is to ensure reliable administration of gas which contains oxygen in a concentration that corresponds to the normal air in the environment/room air without the risk of mixing in odours or other potentially irritating substances. Medicinal air is only indicated as a replacement/substitute for room air, and as soon as it is required it should be mixed with medicinal oxygen so that the desired oxygen concentration is obtained, using the calculation:
FiO_2 = [(number of litres of air/minute x 21) + (number of litres of oxygen/minute x 100] / (number of litres of air/minute + number of litres of oxygen/minute).

Method of administration
Medicinal air is administered via the inspiratory air.
Medicinal air is given via special equipment. With the aid of this equipment medicinal air is added to the gas that is to be inspired, and on expiration the air that has not been absorbed is mixed with the surrounding air (non-rebreathing system). In anaesthesia particularly, special equipment is often used which allows a greater or lesser proportion of the exhaled gas to be recirculated in the respiratory system and rebreathed (so-called rebreathing system).
For information on use and handling, see section 6.6.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

None known.

4.5 Interaction with other medicinal products and other forms of interaction

No known interactions.

4.6 Fertility, pregnancy and lactation

Medicinal air may be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Not relevant.

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 national reporting system listed in Appendix V.

4.9 Overdose

Not relevant.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Medical gases, ATC code V03AN05

Medicinal air contains 21 % oxygen and the remaining part is nitrogen gas, which must be considered inert. Medicinal air is mainly used on account of its oxygen content, which corresponds completely to room air.

Oxygen is vital for human life, and must be supplied continuously to all tissues in order to maintain the cells' energy production. Its target is the mitochondria in the individual cells, where the oxygen takes part in an enzymatic chain reaction, which creates energy, aerobic metabolism.

Nitrogen may be considered as inert.

5.2 Pharmacokinetic properties

Medicinal air consists of 21 % oxygen, which corresponds completely to the concentration in normal room air/surrounding air. It is administered by inhalation and it is transported via the airways to the lungs. In the pulmonary alveoli, as a result of the difference in partial pressure, a gas exchange takes place from the inspired air/gas mixture to the capillary blood. The oxygen is transported further with the systemic circulation, for the most part bound to haemoglobin only a very small part is freely dissolved in plasma, to the capillary beds in the different tissues of the body. The oxygen is transported with the aid of the pressure gradient out to the various cells.

Oxygen that is absorbed in the body is excreted almost completely as carbon dioxide formed in the intermediate metabolism.

Nitrogen is not absorbed. It follows the expiratory air without having undergone any conversion/metabolism.

5.3 Preclinical safety data

None.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 45 °C.
Store the cylinder in a place reserved for medicinal gases (does not apply to the home environment).
The gas cylinder must only be connected to equipment suited for the labelled gas.
Handle with care and secure against falling.
Keep away from strong heat.
Store in a well-ventilated place.

6.5 Nature and contents of container

The shoulder of the gas cylinder is marked with black and white paint (indicating air). The body of the gas cylinder is grey or white (indicating medicinal gas).

Container (incl. material) and valves:
2.5 litre steel or composite gas cylinder with shut-off valve or RP/NR valve, both DIN477/13 or shut-off valve, pressure regulator, quick coupling, flow selector, threaded connection according to DIN 477
4 litre steel or composite gas cylinder with shut-off valve and Pin index connection or shut-off valve, pressure regulator, quick coupling, flow selector, threaded connection according to DIN 477
5 litre steel or composite gas cylinder with shut-off valve, threaded connection according to DIN 477/13 or shut-off valve, pressure regulator, quick coupling, flow selector, threaded connection according to DIN 477
10 litre steel or composite gas cylinder with shut-off valve or RP/NR valve, both DIN477/13 or shut-off valve, pressure regulator, quick coupling, flow selector, threaded connection according to DIN 477
20 litre steel or composite gas cylinder with shut-off valve or RP/NR valve, both DIN477/13 or shut-off valve, pressure regulator, quick coupling, flow selector, threaded connection according to DIN 477
50 litre steel or composite gas cylinder with shut-off valve or RP/NR valve, both DIN477/13 or shut-off valve, pressure regulator, quick coupling, flow selector, threaded connection according to DIN 477
Bundle of 12 x 50 litre steel or composite gas cylinders with shut-off valve, DIN 477/13 or shut-off valve, pressure regulator, quick coupling, flow selector, threaded connection according to DIN 477.

Gas cylinders/bundle filled to 200 bar contain approx. X litres of gas at atmospheric pressure and 15 °C according to the table below:

Cylinder size in litre	2.5	4	5	10	20	50
Litre of gas	500	800	1000	2000	4000	10 000

Bundle size in litre	12x50
Litre of gas	120 000

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

General

Medicinal gases must only be used for medical purposes.

Different gas types and gas qualities must be kept separate from each other. Full and empty gas cylinders must be stored separately.

Never apply oil or grease, even if the cylinder valve is difficult to operate or if the regulator is difficult to connect.
Valves and equipment must be handled with clean and grease-free (hand cream, etc.) hands.

Use only standard equipment that is intended for medicinal air.

The gas cylinders must be protected from wind and weather, and kept dry and clean.
Check that the cylinders are sealed before use.

Remaining pressure at return should be > 2 bar (200 kPa).

Preparation for use

Remove the seal from the valve before use.

Use only regulators intended for medicinal air. Check that the connection on the outside of the coupling or regulator is clean and that the connections are in good condition.
Replace O-ring/seal as recommended by the equipment manufacturer.

Never use a tool on a stuck pressure/flow regulator intended to be connected manually, as this can damage the coupling.

Open the cylinder valve slowly – at least half a turn.

Check for leakage in accordance with the instruction that accompanies the regulator. Do not try to handle leakage from the valve or apparatus yourself other than by changing the gasket or O-ring.

In the event of leakage, close the valve and disconnect the regulator. Label defective cylinders, put them in the area intended for complaints and return them to the supplier.

Using the gas cylinder

Smoking and open fire are prohibited in areas where medicinal air is being used.

Shut the cylinder valve in the event of fire and when not being used.

Larger gas cylinders (> 5 L) should be transported with an appropriate type of cylinder trolley. Take special care that connected devices are not inadvertently loosened.

When the cylinder is in use it must be fixed to a suitable support preventing it from falling.

When a small amount of gas is left in the gas cylinder, the cylinder valve must be closed. It is important to leave a little excess pressure in the cylinder to protect it from becoming contaminated.

After use, the cylinder valve must be closed hand-tight. Depressurise the regulator or connection.

7. MARKETING AUTHORISATION HOLDER

Nippon Sanso Norge AS
P.O.Box 23 Haugenstua
N-0915 Oslo
Norway

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2009-09-30
Date of latest renewal: 2014-09-30

10. DATE OF REVISION OF THE TEXT

04/2026