

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Medicinal Oxygen Air Liquide Santé 100 % inhalation gas for dogs, cats and horses.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

100 % oxygen.

3. PHARMACEUTICAL FORM

Inhalation gas.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats and horses.

4.2 Indications for use, specifying the target species

For oxygen supplementation and as a carrier gas during inhalation anaesthesia.
For oxygen supplementation during recovery.

4.3 Contraindications

None.

4.4 Special warnings <for each target species>

None.

4.5 Special precautions for use

Special precautions for use in animals

Oxygen in concentration up to 100 % (FiO₂ 1.0) should not exceed 12 hours. Oxygen in concentration over 80 % (FiO₂ 0.8) should not exceed 18 hours.

Animals with pre-existing oxygen radical damage to the lung may have this damage exacerbated by oxygen therapy e.g. in the treatment of paraquat poisoning.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This veterinary medicinal product should only be used by persons who have been fully trained to use pressure regulators and associated equipment.

Whilst oxygen is non-flammable, it strongly supports combustion and no naked flames should be allowed near the container. Since even the smallest spark can cause violent ignition, electrical equipment capable of sparking should not be used in the vicinity of patients receiving oxygen.

Cylinder valves and associated equipment must not be lubricated and must be kept entirely free from carbon-based oils and grease because otherwise there is a risk of spontaneous combustion and a violent explosion may occur.

If you have been working in an oxygen-enriched atmosphere avoid smoking, open flames or other sources of ignition for at least 15 minutes.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Medicinal Oxygen Air Liquide Santé can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

Medicinal Oxygen Air Liquide Santé can be safely administered as a carrier gas for inhalation anaesthetics.

4.9 Amounts to be administered and administration route

The precise fresh gas flow rate required by an animal during anaesthesia and recovery should be determined by a suitably experienced veterinarian, taking into consideration the bodyweight and health status of the animal and the anaesthetic equipment and agents being used. The animal must be monitored closely, preferably by means of a pulse oximeter, and the flow rate adapted during anaesthesia to meet their individual requirements.

In-circuit oxygen meters can be used to measure the inspired oxygen fraction and depending on the individual animal, a level of 50 – 100 % of the veterinary medicinal product may be required. As a rule, and if oxygen tension cannot be measured, the inspired oxygen fraction should be maintained at more than 50 %.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Adverse effects can occur if mammals are exposed to excessive levels of oxygen for long periods of time or if high levels of oxygen are administered under hyperbaric conditions. The first signs of oxygen toxicity include dyspnoea and cyanosis, but should only be suspected after at least 12 hours of 100 % oxygen administration or 18 hours of 80 % oxygen administration under normobaric conditions.

In cases where oxygen toxicity is suspected, the fresh gas flow rate should be maintained, but the oxygen concentration of the inspired gas should be reduced to approximately 50 %, or less if adequate oxygenation can be maintained. Oxygenation can be assessed using pulse oximetry or arterial blood gas analysis. The oxygen concentration can be reduced to 50 % by including 50 % nitrogen or approximately 60 % medical air. This is best monitored with an in-circuit oxygen monitor. Alternatively, supplementary oxygen can be given to an animal breathing air, and the flow rate adjusted to provide the appropriate inspired concentration.

4.11 Withdrawal period(s)

Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Medical Gases, ATCvet code: QV03AN01.

5.1 Pharmacodynamic properties

Oxygen is an essential element for living organisms. It is involved in cellular metabolism and catabolism and permits production of energy in the form of adenosine triphosphate (ATP). The variation of the partial pressure of oxygen in the blood affects the cardiovascular system, the respiratory system, cellular metabolism, and the central nervous system. Deprivation of oxygen, resulting in tissue hypoxia, results in a rapid deterioration of myocardial and central nervous activity. Intervention with oxygen therapy is essential for the resolution of adequate tissue oxygenation.

5.2 Pharmacokinetic particulars

Oxygen administered by inhalation is absorbed by alveolar-capillary exchange. It is present in the plasma in the solution and is transported by erythrocytes in the form of oxyhaemoglobin. Oxygen released at tissue level by oxyhaemoglobin is then used in mitochondria for the synthesis of ATP. Following these catalytic reactions it reappears in the form of CO₂ and H₂O. Both metabolised and excess, unmetabolised oxygen are eliminated from the body during exhalation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:

5 years.

6.4 Special precautions for storage

Cylinders should be stored in a locked, clean and ventilated area reserved for the storage of medical gases, protected from weather and with no inflammable materials. Full and empty cylinders should be stored separately. Cylinders should be protected from falling, from being hit, from sources of heat or ignition, from temperatures of more than 50 °C and from combustible materials. Cylinders must be kept vertical.

6.5 Nature and composition of immediate packaging

15 l and 50 l metal cylinders with pressure control valves (body and nozzle painted in white).

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Unwanted partially full, or empty, Medicinal Oxygen Air Liquide Santé cylinders should be returned to the manufacturer or their authorised distributor.

7. MARKETING AUTHORISATION HOLDER

AIR LIQUIDE Santé INTERNATIONAL
10, rue Cognacq-Jay
75341 Paris Cedex 07
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/067/001
EU/2/06/067/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20.12.2006

10. DATE OF REVISION OF THE TEXT

20.12.2006

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (EMA) <http://www.ema.europa.eu>

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

- A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE**
- C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE**
- D. STATEMENT OF THE MRLs**

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Air Liquide Santé France
Zone Industrielle Est
BP 34
F-54181 Heillecourt
France

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable

ANNEX III

LABELLING AND PACKAGE LEAFLET

Medicinal product no longer authorised

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Information to appear on a durable plastic label appended directly to the cylinder body.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Medicinal Oxygen Air Liquide Santé 100 % inhalation gas for dogs, cats and horses.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

100 % oxygen.

3. PHARMACEUTICAL FORM

Inhalation gas.

4. PACKAGE SIZE

15 l cylinders filled at 200 bar, containing 3.2 m³ oxygen under a pressure of 1 bar at 15 °C.
50 l cylinders filled at 200 bar, containing 10.6 m³ oxygen under a pressure of 1 bar at 15 °C.

5. TARGET SPECIES

Dogs, cats and horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Keep away from naked flames.
Do not lubricate.
No smoking.

10. EXPIRY DATE

EXP {MM/AAAA}

11. SPECIAL STORAGE CONDITIONS

Cylinders should be stored in a locked, clean and ventilated area reserved for the storage of medical gases, protected from weather and with no inflammable materials. Full and empty cylinders should be stored separately. Cylinders should be protected from falling, from being hit, from sources of heat or ignition, from temperatures of more than 50 °C and from combustible materials. Cylinders must be kept vertical.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Unwanted partially full, or empty, Medicinal Oxygen Air Liquide Santé cylinders should be returned to the manufacturer or their authorised distributor.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

AIR LIQUIDE Santé INTERNATIONAL
10, rue Cognacq-Jay
75341 Paris Cedex 07
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/067/001 - 151
EU/2/06/067/002 - 501

17. MANUFACTURER'S BATCH NUMBER

Medicinal product no longer authorised

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Medicinal Oxygen Air Liquide Santé 100 % inhalation gas for dogs, cats and horses.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

AIR LIQUIDE Santé INTERNATIONAL
10, rue Cognacq-Jay
75341 Paris Cedex 07
FRANCE

Manufacturer for the batch release:

AIR LIQUIDE Santé FRANCE
ZI Est, BP 34
54181 Heillecourt Cedex
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Medicinal Oxygen Air Liquide Santé 100 % inhalation gas for dogs, cats and horses.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Medicinal Oxygen Air Liquide Santé is an inhalation gas consisting of 100 % oxygen.

4. INDICATION(S)

Medicinal Oxygen Air Liquide Santé can be used for oxygen supplementation and as a carrier gas during inhalation anaesthesia.

The veterinary medicinal product can also be used for oxygen supplementation during recovery.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None.

7. TARGET SPECIES

Dogs, cats and horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The precise fresh gas flow rate required by an animal during anaesthesia and recovery should be determined by a suitably experienced veterinarian, taking into consideration the bodyweight and health status of the animal and the anaesthetic equipment and agents being used. The animal must be monitored closely, preferably by means of a pulse oximeter, and the flow rate adapted during anaesthesia to meet their individual requirements.

9. ADVICE ON CORRECT ADMINISTRATION

In-circuit oxygen meters can be used to measure the inspired oxygen fraction and depending on the individual animal, a level of 50 – 100 % of the veterinary medicinal product may be required. As a rule, and if oxygen tension cannot be measured, the inspired oxygen fraction should be maintained at more than 50 %.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Cylinders should be stored in a locked, clean and ventilated area reserved for the storage of medical gases, protected from weather and with no inflammable materials. Full and empty cylinders should be stored separately. Cylinders should be protected from falling, from being hit, from sources of heat or ignition, from temperatures of more than 50 °C and from combustible materials. Cylinders must be kept vertical.

Do not use after {Month/Year}.

12. SPECIAL WARNING(S)

Pregnancy and lactation

Medicinal Oxygen Air Liquide Santé can be used during pregnancy and lactation.

Incompatibilities

Medicinal Oxygen Air Liquide Santé has no known incompatibilities with other products likely to be administered concomitantly

Overdose

Due to the high partial pressure of oxygen inhaled by animals during the administration of the veterinary medicinal product, oxygen toxicity may be seen in animals after extended periods of use. The first signs of oxygen toxicity include dyspnoea and cyanosis, but should only be suspected after at least 12 hours of 100 % oxygen administration or 18 hours of 80 % oxygen administration under normobaric conditions. In cases where oxygen toxicity is suspected, the fresh gas flow rate should be maintained, but the oxygen concentration of the inspired gas should be reduced to approximately 50 % or less if adequate oxygenation can be maintained. Oxygenation can be assessed using pulse oximetry or arterial blood gas analysis. The oxygen concentration can be reduced to 50 % by including 50 % nitrogen or approximately 60 % medical air. This is best monitored with an in-circuit oxygen monitor. Alternatively, supplementary oxygen can be given to an animal breathing air, and the flow rate adjusted to provide the appropriate inspired concentration.

Special precautions for use in animals

Oxygen in concentration up to 100 % (FiO₂ 1.0) should not exceed 12 hours. Oxygen in concentration over 80 % (FiO₂ 0.8) should not exceed 18 hours.

Animals with pre-existing oxygen radical damage to the lung may have this damage exacerbated by oxygen therapy e.g. in the treatment of paraquat poisoning.

Precautions to be taken by the person administering the veterinary medicinal product to animals

Medicinal Oxygen Air Liquide Santé should only be used by persons who have been fully trained to use pressure regulators and associated equipment.

Whilst oxygen is non-flammable, it strongly supports combustion and no naked flames should be allowed near the container. Since even the smallest spark can cause violent ignition, electrical equipment capable of sparking should not be used in the vicinity of patients receiving oxygen.

Cylinder valves and associated equipment must not be lubricated and must be kept entirely free from carbon-based oils and grease because otherwise there is a risk of spontaneous combustion and a violent explosion may occur.

If you have been working in an oxygen-enriched atmosphere avoid smoking, open flames or other sources of ignition for at least 15 minutes.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Unwanted partially full, or empty, Medicinal Oxygen Air Liquide Santé cylinders should be returned to the manufacturer or their authorised distributor.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

20.12.2006

Detailed information on this product is available on the website of the European Medicines Agency (EMA) <http://www.emea.europa.eu>

15. OTHER INFORMATION

Pack sizes

15 l cylinders filled at 200 bar, containing 3.2 m³ oxygen under a pressure of 1 bar at 15 °C.
50 l cylinders filled at 200 bar, containing 10.6 m³ oxygen under a pressure of 1 bar at 15 °C.

Lot number

Lot {Number}