



EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

MEDICINAL OXYGEN AIR LIQUIDE SANTÉ

EPAR summary for the public

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use. This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Medicinal Oxygen Air Liquide Santé?

Medicinal Oxygen contains oxygen extracted as a free gas from the atmosphere (the air we breathe). It is presented as 15- or 50-litre steel cylinders containing compressed oxygen gas.

What is Medicinal Oxygen Air Liquide Santé used for?

Medicinal Oxygen is used to provide oxygen in dogs, cats and horses who have been anaesthetised and are not breathing naturally. It is also given after anaesthesia to help recovery. It can also be used as a carrier gas for other gases used to anaesthetise the animal.

How does Medicinal Oxygen Air Liquide Santé work?

Oxygen is an essential element for living organisms. It is absorbed from the air into the blood through the lungs (respiration). Intervention with oxygen therapy is therefore important in certain cases to ensure adequate tissue oxygenation.

How has Medicinal Oxygen Air Liquide Santé been studied?

Oxygen is a well-established medical gas that has been in use for many years, and the company used information from the published literature. They provided satisfactory information on the quality, the safety of the medicine in dogs, cats and horses and its safety in humans (people in contact with the product) and the environment.

Further information was provided on the benefits of oxygen supplementation during anaesthesia and recovery.

What benefit has Medicinal Oxygen Air Liquide Santé shown during the studies?

The literature provided by the Applicant supported the recommendations in the SPC for oxygen supplementation during anaesthesia and recovery in dogs, cats and horses.

What is the risk associated with Medicinal Oxygen Air Liquide Santé?

Medicinal Oxygen has no side effects.

The principal risks associated with the use of this medicine are the inadvertent release of pressurised gas following incorrect use and the increased fire risks associated with localised increased oxygen concentrations.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

This product should only be used by persons who are trained in the use of compressed gas and associated equipment.

Why has Medicinal Oxygen Air Liquide Santé been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of oxygen supplementation during anaesthesia and recovery in dogs, cats and horses exceed the risks associated with its use. However, it is noted that the rate of oxygen supplementation required by an animal varies depending on a variety of factors, and that the appropriate oxygen 'dose' to use during anaesthesia for a given animal must be established by the attending veterinarian, and continually monitored during anaesthesia.

Other information about Medicinal Oxygen Air Liquide Santé:

The European Commission granted a marketing authorisation valid throughout the European Union, for Medicinal Oxygen Air Liquide Santé to Air Liquide Santé International on 20.12.2006. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 20.12.2006.