



EUROPEAN MEDICINES AGENCY  
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## **EPAR summary for the public**

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# Oxyglobin

## Haemoglobin glutamer 200

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 Oxyglobin?**

Oxyglobin contains bovine haemoglobin glutamer-200 (at a strength of 130 mg/ml), which belongs to a class of medicines having an oxygen-carrying action. Oxyglobin is a solution for infusion (drip into a vein).

### **What is Oxyglobin used for?**

Oxyglobin is used to increase the oxygen content of the blood in dogs with anaemia (low red blood cell count). Oxyglobin should be used for at least 24 hours.

Oxyglobin is first warmed to 37°C, then given to the dog as 30 ml per kilogram body weight, administered at a rate of up to 10 ml/kg per hour. The most appropriate dose depends on the severity of the anaemia and how long the dog has been anaemic, as well as the desired duration of the medicine's effect. Oxyglobin is intended for a single use only. Oxyglobin does not need to be matched to the dog's blood type. For further information, see the Package Leaflet.



## **How does Oxyglobin work?**

Oxyglobin is a haemoglobin-based oxygen-carrying solution. It contains haemoglobin glutamer-200, which is made from haemoglobin (the protein in red blood cells that carries oxygen around the body) extracted from cows' blood and diluted in a standard solution (Ringer's lactate) used to replace blood volume. When Oxyglobin is given to dogs, it increases the amount of haemoglobin in the blood, as well as increasing the volume of blood in the body. This increases the amount of oxygen carried in the blood in the arteries, helping to reduce the symptoms of anaemia.

## **How has Oxyglobin been studied?**

Oxyglobin has been tested in a study of dogs with short or long-term anaemia due to conditions such as blood loss, the abnormal breakdown of red blood cells or low levels of red blood cell production. The study compared the effects of Oxyglobin with no treatment.

## **What benefit has Oxyglobin shown during the studies?**

In the main study in dogs, 95% of the animals treated with Oxyglobin needed no other type of oxygen-carrying treatment after 24 hours, compared with 32% of the dogs that did not receive any treatment. It took longer until additional treatment was needed in dogs treated with Oxyglobin. The medicine also increased levels of haemoglobin in the blood and improved the dogs' physical condition.

Additional studies supported these results, showing that Oxyglobin can take up, transport and release oxygen in animals other than cows. This oxygen can then be supplied to tissues such as muscle.

## **What is the risk associated with Oxyglobin?**

The side effects seen with Oxyglobin are caused both by the medicine and by the underlying cause of the anaemia. They include discoloration of the skin, mucous membranes (lining of body cavities) and sclera (whites of the eyes), dark faeces and discoloured or turbid (opaque) urine. A common side effect is 'circulatory overload' (when the blood fluid leaks out of the blood vessels), which causes tachypnea (rapid breathing), dyspnea (shortness of breath), harsh lung sounds and pulmonary oedema (fluid accumulation in the lungs). Other common side effects are vomiting, loss of appetite and fever. For a full list of all side effects reported with Oxyglobin, see the Package Leaflet.

Oxyglobin should not be used in animals that have received Oxyglobin in the past, or in dogs that are at an increased risk of circulatory overload with conditions such as oliguria or anuria (infrequent or no urination) or advanced heart disease.

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

There are no precautions necessary.

## **Why has Oxyglobin been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Oxyglobin exceed the risks for the provision of oxygen-carrying support to dogs improving the clinical signs of anaemia for at least 24 hours, independent of the underlying condition, and recommended that Oxyglobin be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

## **Other information about Oxyglobin:**

The European Commission granted a marketing authorisation valid throughout the European Union for Oxyglobin on 14 July 1999. Information on the prescription status of this product may be found on the label of the carton.

This summary was last updated in March 2012.