PARTICULARS TO APPEAR ON THE OUTER PACKAGE Aluminium Overwrap & Carton Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxmax 65 mg/ml solution for infusion for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 65 mg hemoglobin betafumaril (bovine)

3. PACKAGE SIZE

100 ml (Aluminium overwrap)
2 x 100 ml (Carton box)

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {month/year}

Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

New Alpha Innovation Biopharmaceutical Ireland Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 51132/5000

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE Infusion Bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxmax 65 mg/ml solution for infusion for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 65 mg hemoglobin betafumaril (bovine)

3. TARGET SPECIES

Dogs

4. ROUTES OF ADMINISTRATION

Intravenous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

EXP {month/year}

Once opened use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2 °C – 8 °C)

Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

New Alpha Innovation Biopharmaceutical Ireland Limited

9. BATCH NUMBER

Lot

10. SPECIAL WARNING(S), IF NECESSARY

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxmax 65 mg/ml solution for infusion for dogs

2. COMPOSITION

Each ml contains:
65 mg hemoglobin betafumaril (bovine)

Dark purple solution.

3. TARGET SPECIES

Dogs

4. INDICATIONS FOR USE

Indicated as an adjunct therapy in the management of canine haemorrhagic shock. A beneficial effect of treatment was demonstrated for 24 hours survival rate when the veterinary medicinal product was administered concomitantly with low dose resuscitative fluids (Lactated Ringer's solution).

5. CONTRAINDICATIONS

Do not use in dogs with identified kidney disease.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in animals at risk of volume overload (e.g. animals with oliguria/anuria or advanced cardiac disease) as this may cause adverse effects associated with circulatory overload.

Do not use in dogs previously treated with this veterinary medicinal product or other bovine haemoglobin-based oxygen carriers, to avoid a potential sensitivity-type reaction following repeated exposure.

6. SPECIAL WARNINGS

There is no efficacy data available for dogs that have been rehydrated prior to administration of the product or in cases of normovolaemic anaemia.

Special precautions for use in animals

To be used as single administration.

Avoid food and water for the duration of administration.

The indication for use was established following the concomitant administration of the product and crystalloid resuscitative fluids (LRS). In the absence of a critical

clinical situation, the product should not be administered to dogs that have already received fluid therapy to restore circulatory volume.

Due to the plasma expanding properties of the veterinary medicinal product, the possibility of circulatory overload and pulmonary oedema should be considered and monitored, especially when administering adjunctive intravenous fluids, particularly colloidal solutions.

Signs of circulatory overload should be carefully monitored. Rapid blood volume expansion may be controlled by slowing the rate of administration. If circulatory overload occurs, cease the infusion immediately, and consider administering diuretics.

Renal function should be monitored during and after use of the veterinary medicinal product. If clinical signs of renal impairment such as depression, reduced food intake, vomiting, polyuria or oliguria are noted, renal function should be assessed. Results of serum chemistry parameters to evaluate renal function should be interpreted with care, as the presence of the veterinary medicinal product at the recommended treatment dose may interfere with the results for BUN, CREA (Creatinine), BUN/CREA ratio and Urea. These are likely to be unreliable markers of renal function up to 12 hours (Urea) and up to 4 days (BUN, BUN/CREA ratio and CREA) after administration. Appropriate treatment should be instigated if impaired renal function is evident. Renal function can be assessed using tools such as abdominal ultrasound and urinalysis (specifically urine sediment examination and urine specific gravity measurement).

In the event of anaphylaxis, clinical signs that include a skin rash, swelling of the face or extremities, difficulty in breathing and/or vomiting will occur. If anaphylaxis does occur, treat symptoms immediately as considered appropriate, for example with adrenaline followed by corticosteroids.

Clinical pathology:

In dogs with pre-existing haemolysis, routine analysis will not be able to distinguish the veterinary medicinal product from native haemoglobin in the plasma.

Chemistry and haematology:

The presence of the veterinary medicinal product in serum may interfere with colourimetric readings and result in erroneous increases, or decreases, in the results of serum chemistry and haematology tests depending on the dose administered, the time after infusion, the type of analyser and the reagents used.

Measurement of lactate in canine blood may be affected by the presence of the veterinary medicinal product. It is advised to interpret the measured lactate concentration with caution, and to use other parameters in combination with lactate levels for clinical evaluation of the patient.

Coagulation:

Prothrombin time (PT) and activated partial thromboplastin time (aPTT) can be accurately determined in the presence of the veterinary medicinal product using methods that are either mechanical, magnetic, or light scattering. Colourimetric

methods may not be reliable for coagulation assays in the presence of the veterinary medicinal product.

Urinalysis:

Sediment examination and specific gravity measurements are accurate in the presence of the veterinary medicinal product. Dipstick measurements (e.g. pH, glucose, ketones, and protein) and gravity measurement using a refractometer, are likely to be inaccurate if there is visible discolouration of the urine.

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

In a good laboratory practice (GLP) target animal safety study, two intravenous infusions of the veterinary medicinal product at dose levels of up to 90 ml/kg bodyweight were generally well-tolerated by male and female Beagle dogs.

Treatment-related renal histopathology change was seen in this study at all dose levels (30, 60 and 90 ml/kg bw); however the findings were reversible and are attributed to the effects of increased levels of free haemoglobin.

The presence of renal pathology, though reversible, suggests that 90 ml/kg bw may be close to the maximum tolerable dose.

Overdose or an excessive rate of administration (that is, more than 10 ml/kg/h) could result in immediate cardiopulmonary effects. If this occurs, discontinue the infusion of the veterinary medicinal product immediately until signs abate. Treatment of circulatory overload may be necessary.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

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

If adverse reactions develop following accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

This product contains bovine-derived haemoglobin. There is a risk that immune mediated reactions (hypersensitivity reactions) may occur in sensitised persons if repeated accidental self-injection occurs. In case of hypersensitivity reactions, seek medical advice immediately and show the package leaflet or the label to the physician. Do not handle or administer the product if a previous hypersensitivity reaction has occurred.

N-acetyl-L-cysteine is an excipient in this veterinary medicinal product and has been associated with hypersensitivity reactions in humans following intravenous infusion. People with known hypersensitivity to N-acetyl-L-cysteine should take care to avoid accidental self-injection with this veterinary medicinal product.

Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. ADVERSE EVENTS

Very common (>1 animal / 10 animals treated):	Diarrhoea, Abnormal stool colouration, Blood in faeces NOS, Vomiting, Shivering, Sneezing, Injection site reddening, Injection site swelling
Common (1 to 10 animals / 100 animals treated):	Discoloured urine, Discoloration of tissue (necropsy finding), Discolouration of mucous membrane (necropsy finding)

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Intravenous use.

The recommended dose is 10 ml/kg bodyweight administered intravenously at a rate of up to 10 ml/kg/hour, to be administered concomitantly with low dose crystalloid fluids (Lactated Ringer's solution, at a dose of 20 ml/kg/hour).

9. ADVICE ON CORRECT ADMINISTRATION

For intravenous use only.

To be used as single administration.

Administer using aseptic technique via a standard intravenous infusion set and catheter.

Do not administer in combination with other fluids or medicinal products using the same infusion set.

The veterinary medicinal product should be brought to room temperature prior to administration. Do not microwave.

Typing or cross-matching of the recipient's blood is not required before using this veterinary medicinal product.

Due to possible interference with assay results (see section 6), it is advisable to obtain clinical samples (blood, urine) for all necessary clinical tests before administration of this veterinary medicinal product.

The veterinary medicinal product should not be used if there is any colour change or any visible particulate in the dark purple solution or if the package is found damaged.

10. WITHDRAWAL PERIODS

11. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

100 ml (Aluminium overwrap)
2 x 100 ml (Carton box)

Vm 51132/5000

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
New Alpha Innovation Biopharmaceutical Ireland Limited
The Black Church
St. Mary’s Place
Dublin
D07 P4AX
Ireland
+353 1 443 3800

Manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Klifovet GmbH
Geyerspergerstr. 27
80689 München
Germany
+49 89 580082019
Pharmacovigilance_qppv@klifovet.de

17. OTHER INFORMATION

POM-V

Approved 28 November 2023