NDC #

Oxαpex® IDX

(Hemoglobin crosfumaril (bovine) injection) 65 mg/mL

For use in captive mustelids, captive rodents, raptors, and captive or pet birds of the orders Psittaciformes, Passeriformes, and Columbiformes. For intravenous or intraosseous use only.

NOT APPROVED BY FDA — Legally marketed as an FDA Indexed Product under MIF 900-018. Extra-label use is prohibited. This product is not to be used in animals intended for use as food for humans or other animals.

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DIRECTIONS: Refer to package insert for complete directions for use. Store below 25 °C (77 °F) in a dry place and protect from light. Do not freeze. For single use only. Discard any unused portion after opening.

New α Innovation

Front label

INDICATION: Oxapex® IDX is intended for the treatment of anemia; specifically to resolve hypoxemia associated with imminent anemic crisis caused by blood loss, hemolysis, or reduced hematopoiesis in captive mustelids, captive rodents, raptors, and captive or pet birds of the orders Psittaciformes, Passeriformes, and Columbiformes, excluding squab raised for food.

Use only when there is a reasonable certainty that the treated animal will not be consumed by humans or food-producing animals.

WARNINGS: Not for use in humans. Keep out of reach of children.

MANUFACTURED BY: New A Innovation Limited, Hong Kong
www.newainnovation.com

DISTRIBUTED BY:

NET CONTENT: 20 mL Lot: Exp:

Back label

NDC #

Oxαpex® IDX

(Hemoglobin crosfumaril (bovine) injection) 65 mg/mL

For use in captive mustelids, captive rodents, raptors, and captive or pet birds of the orders Psittaciformes, Passeriformes, and Columbiformes. For intravenous or intraosseous use only.

NOT APPROVED BY FDA — Legally marketed as an FDA Indexed Product under MIF 900-018. Extra-label use is prohibited. This product is not to be used in animals intended for use as food for humans or other animals.

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DIRECTIONS: Refer to package insert for complete directions for use. Store below 25 °C (77 °F) in a dry place and protect from light. Do not freeze. For single use only. Discard any unused portion after opening.

POUCH CONTAINS: One 20 mL bag

Lot: Exp:

New α Innovation

Overwrap label

Oxapex® IDX

(Hemoglobin crosfumaril (bovine) injection)
65 mg/mL

NOT APPROVED BY FDA

Legally marketed as an FDA Indexed Product under MIF 900-018. For use in captive mustelids, captive rodents, raptors, and captive or pet birds of the orders Psittaformes, Passeriformes, and Columbiformes. Extra-label use is prohibited. This product is not to be used in animals intended for use as food for humans or other animals. CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Oxapex® IDX is an injectable solution consisting of hemoglobin crosfumaril (bovine) as the active substance at a concentration of 65 mg/mL. Hemoglobin crosfumaril (bovine), which has a molecular weight of 65 kDa, is formulated in a Ringer's acetate solution (containing sodium chloride, potassium chloride, calcium chloride dehydrate and sodium acetate trihydrate) with addition of sodium hydroxide, acetic acid, glacial, water for injection and 0.2% of N-acetyl-L-cysteine. The sterile solution is deep purple in color with a pH range of 7.2-7.6 and an osmolality range of 250-350 mOsm/kg.

INDICATIONS

Oxapex® IDX is intended for the treatment of anemia; specifically to resolve hypoxemia associated with imminent anemic crisis caused by blood loss, hemolysis, or reduced hematopoiesis in captive mustelids, captive rodents, raptors, and captive or pet birds of the orders Psittaciformes, Passeriformes, and Columbiformes, excluding squab raised for food.

Oxapex® IDX should be used only when there is a reasonable certainty that the treated animal will not be consumed by humans or food-producing animals.

DOSAGE AND ADMINISTRATION

Each 20 mL bag of Oxapex® IDX is intended for single use only. Use aseptic technique to administer the product intravenously or via intraosseous catheter appropriate for the animal species.

The recommended dose of Oxapex® IDX is 5–10 mL/kg (0.5–1 mL/100 grams) of body weight or an administration rate for slow bolus of 1-3 mL/kg/hour.

The actual dose-to-effect should be based upon the assessment of the animal's clinical status by the veterinarian. Discard any unused portion after opening.

CONTRAINDICATIONS

Do not use Oxapex® IDX in animals with known hypersensitivity to this product or other bovine source proteins.

HUMAN SAFETY WARNINGS

Not for use in humans. Keep out of reach of children.

In case of accidental human injection, a physician should be consulted. In case of skin or eye contact, flush affected area with water.

PRECAUTIONS

If anaphylaxis is evident, treat immediately with appropriate medical intervention.

The presence of Oxapex® IDX in serum and urine may interfere with colorimetric readings and result in erroneous increases or decreases in the results of serum chemistry, hematology tests and urine analysis depending on the dose administered, the time since infusion, the type of analyzer and the reagents used.

In patients with pre-existing hemolysis, routine analysis will not be able to distinguish Oxapex® IDX from native hemoglobin in plasma.

ADVERSE REACTIONS

Adverse reactions to administration of Oxapex® IDX may include vomiting, sneezing and discoloration of mucous membranes, tissues, urine and feces. Reactions at the site of infusion (redness and/or swelling) may also occur.

To report suspected adverse drug events, please call 1-604-421-7308. Adverse drug reactions may also be reported to the FDA/CVM at: 1-888-FDA-VETS or http://www.fda.gov/AnimalVeterinary/SafetyHealth.

PHARMACOLOGY

Oxapex® IDX contains hemoglobin crosfumaril (bovine). Since the hemoglobin is not constrained by a cellular membrane (free in plasma), it is free to distribute throughout the vascular system. The hemoglobin transports and supplies oxygen to cells; increasing plasma hemoglobin levels leads to an increase in oxygen-carrying content.

Oxapex® IDX is not intended as a volume expander or replacement but is intended to improve oxygen delivery.

DISPOSAL

The opened container of Oxapex® IDX should be disposed of following initial use and should not be retained or stored for future use.

Unused solution should be disposed of in accordance with local environmental requirements.

STORAGE

Store below 25 °C (77 °F) in a dry place and protect from light. Do not freeze.

HOW SUPPLIED

Oxapex® IDX is supplied in infusion bags containing 20 mL of hemoglobin crosfumaril (bovine) solution. Each infusion bag is sealed within an overwrap pouch.

MANUFACTURED BY

New A Innovation Limited
17/F, Chevalier Commercial Centre, 8 Wang Hoi Road,
Kowloon Bay, Kowloon, Hong Kong
www.newainnovation.com

NDC#

For technical assistance please call 1-604-421-7308.

Package insert