PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dopram®-V Injection 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance - Doxapram Hydrochloride 20 mg (equivalent to 17.5 mg doxapram).

Excipients - Chlorobutanol hemihydrate 5 mg (antimicrobial preservative) and Water for Injection qs to 1ml.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Dogs, cats and horses.

Neonate dogs, cats, calves and lambs.

6. INDICATION(S)

Respiratory stimulant for dogs, cats and horses, and for neonate dogs, cats, calves and lambs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Sterile solution for parenteral and topical sublingual use

8. WITHDRAWAL PERIOD

For horses and neonatal calves and lambs, the meat withdrawal period is 28 days from last administration.

Not intended for use in animals producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Dopram-V is incompatible with alkaline solutions such as aminophylline, frusemide and thiopental.

Avoid self-injection with the product

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from frost. Protect from light.

Shelf life after first opening the immediate packaging: 28 days.

Keep the container in the outer carton.

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

Discard unused material.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4038

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dopram®-V Injection 20 mg/ml Solution for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 1 ml contains:
Active substance: Doxapram Hydrochloride 20 mg (equivalent to 17.5 mg doxapram).

Excipients: Chlorobutanol hemihydrate 5 mg (antimicrobial preservative) and Water for Injections qs to 1 ml.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTE(S) OF ADMINISTRATION

For use in dogs, cats, horses, calves and lambs.
Consult package leaflet before use.

5. WITHDRAWAL PERIOD

Horses, neonatal calves and lambs: meat and offal - 28 days.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

FOR ANIMAL TREATMENT ONLY

Keep out of the sight and reach of children.

Shelf life after first opening the immediate packaging: 28 days. Discard unused material.

Do not store above 25°C. Protect from frost. Protect from light. Keep container in outer carton

POM-V

To be supplied only on veterinary prescription

Vm 42058/4038

PACKAGE LEAFLET FOR: Dopram-V Injection 20 mg/ml Solution for Injection

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

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

Manufacturer:
Norbrook Laboratories Ltd
Station Works, Newry
Co. Down, N. Ireland
BT35 6JP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dopram®-V Injection 20 mg/ml Solution for Injection

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

Dopram-V Solution for Injection is presented in multi-dose vials containing 20 ml of sterile solution for parenteral and topical sublingual use.

Each ml contains:

Active substance: Doxapram hydrochloride 20 mg (equivalent to 17.5 mg doxapram).

Excipients: Chlorobutanol hemihydrate 5 mg (antimicrobial preservative) and Water for Injections qs to 1ml.

4. INDICATION(S)

Dopram-V (doxapram hydrochloride) is a potent respiratory stimulant. It differs from the analeptic agents in having greater specificity of action on the respiratory centre.

Respiratory stimulant.
For dogs, cats and horses:
1. To stimulate respiration during and after general anaesthesia.
2. To speed awakening and return of reflexes after anaesthesia when this is considered beneficial.

Neonatal puppies, kittens, calves and lambs:
1. To initiate respiration following dystocia or Caesarean section.
2. To stimulate respiration following dystocia or Caesarean section.

5. CONTRAINDICATIONS

Dopram-V Injection is contra-indicated for use in food producing animals with the exception of neonatal calves, lambs, and horses.

6. ADVERSE REACTIONS

Excessive doses may produce hyperventilation, which may be followed by reduced carbon dioxide tension in the blood, cerebral vasoconstriction, hypoxia and possible brain damage.

Excessive doses administered to animals during, or following anaesthesia with cyclopropane or halogenated hydrocarbon anaesthetics may precipitate cardiac arrhythmias.

7. TARGET SPECIES

Dogs, cats and horses.

Neonate dogs, cats, calves and lambs.

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

To ensure adequate dosing an insulin-type syringe must be used for administration to low bodyweight animals.
Post anaesthetic use: For intravenous use only.

Dogs and cats:
Following intravenous anaesthesia 2-5 mg/kg (0.1-0.25 ml/kg) depending on response.
Following inhalation anaesthesia 1-2 mg/kg (0.05-0.1 ml/kg) depending on response.
Dosage should be adjusted for depth of anaesthesia and degree of respiratory depression. Dosage can be repeated in 15 to 20 minutes if necessary.

Horses:
Following intravenous or inhalation anaesthesia 0.5-1.0 mg/kg (2.5-5.0 ml/100 kg) depending on response. Dosage should be adjusted for depth of anaesthesia and degree of respiratory depression.

Neonatal use:
Puppies:
For intravenous or subcutaneous injection and for topical sublingual use.
1-5 mg (0.05-0.25 ml) depending on size of neonate and degree of respiratory depression.

Kittens:
For intravenous or subcutaneous injection and for topical sublingual use.
1-2 mg (0.05-0.1 ml) depending on size of neonate and degree of respiratory depression.

Calves:
For intravenous, intramuscular, subcutaneous or sublingual use.
40-100 mg (2.0-5.0 ml) depending on size of neonate and degree of respiratory depression.

Lambs:
For intravenous, subcutaneous or sublingual use.
5-10 mg (0.25-0.5 ml) depending on size of neonate and degree of respiratory depression.

The action of Dopram-V is rapid, usually beginning in a few seconds. The duration and intensity of response depends on the dose, the condition of the animal at the time the drug is administered and depth of anaesthesia.
Repeated doses should not be given until the effects of the first dose have passed, and the condition of the patient requires it.
However, the therapeutic ratio (convulsive dose: respirogenic dose) is very high. In trials carried out on conscious cats to determine the total dose required to initiate hyperventilation compared to the total dose required to produce convulsions, the convulsive dose to respirogenic dose was calculated to be 38:1.

9. ADVICE ON CORRECT ADMINISTRATION

Dosage of Dopram-V should be adjusted to meet the requirements of the situation.

Adequate, but not excessive, doses should be used. A patent airway is essential. Reflexes should be checked periodically.

10. WITHDRAWAL PERIOD(S)

Horses, neonatal calves and lambs: meat and offal - 28 days.

Not intended for use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC. Protect from frost. Protect from light.

Keep container in outer carton.

Shelf life after first opening the immediate packaging: 28 days.

When the container is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded, should be worked out. This discard date should be written in the space provided on the label.

Discard any unused material

12. SPECIAL WARNING(S)

Dopram-V Injection should be administered with extreme caution in dogs that have been sedated with morphine. Administration of Dopram-V Injection at a dose of 10 mg/kg to such animals may be followed by convulsions.

Dopram-V Injection is incompatible with alkaline solutions such as aminophylline, frusemide and thiopental.

Operator Warning
Avoid self-injection with the product. Avoid direct contact with skin and eyes.

In the event of contact, wash with plenty of water. If irritation or other symptoms persist, seek medical advice.

Do not smoke, eat or drink when using the product. Wash hands after use.

Keep out of the sight and reach of children.

For animal treatment only

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2017

15. OTHER INFORMATION

Dopram-V Injection has been used extensively in the treatment of exotic species. Doses of 1 mg/kg have been used; the dose being adjusted according to response and the overall condition of the animal. It has been found to be of particular use in the treatment of respiratory failure associated with lungworm infestation in pinnipeds, respiratory depression produced by barbiturate poisoning in felines and in the anaesthetic management of the giraffe.

The metabolism of doxapram has been studied in the dog and man. Doxapram is extensively metabolised; the metabolites and unchanged doxapram are excreted in the bile and urine. The pharmacokinetic properties of doxapram can be described by a multi-compartmental model. Due to rapid redistribution the pharmacological effects of an intravenous injection of doxapram are terminated within 15-20 minutes following administration.

Package quantities

Dopram-V Injection is available in 20 ml multi-dose vials.

Dopram-V is also available in 5 ml dropper bottles for topical sublingual use.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4038

Approved: 13/04/2017