

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dopram®-V Drops 20 mg/ml oral drops solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1 ml contains:

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

Excipients:

Chlorobutanol hemihydrate 5 mg (antimicrobial preservative).

3. PHARMACEUTICAL FORM

Oral drops, solution

4. PACKAGE SIZE

5 ml

5. TARGET SPECIES

Neonate dogs, cats, calves and lambs.

6. INDICATION(S)

To initiate or stimulate respiration in neonate (new born) dogs, cats, calves and lambs following dystocia (difficult birth) or caesarean section.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For sublingual use only

8. WITHDRAWAL PERIOD

Neonatal lambs and calves: meat: 28 days.

Do not use in animals producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

ENSURE AIRWAY IS NOT OBSTRUCTED BEFORE USE

Consult package leaflet before use for contraindications and warnings.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Protect from light. Store in a refrigerator (+2°C to +8°C). Protect from frost.

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

Keep container in 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-VPS

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 42058/4037

17. MANUFACTURER’S BATCH NUMBER

Lot:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dopram®-V Drops 20 mg/ml oral drops solution

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).

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

5 ml

4. ROUTE(S) OF ADMINISTRATION

FOR SUBLINGUAL USE ONLY.

Consult package leaflet before use for contraindications and warnings.

5. WITHDRAWAL PERIOD

Meat: 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.

Store in a refrigerator (+2°C to +8°C). Protect from frost. Keep container in outer carton

POM-VPS

To be supplied only on veterinary prescription

Vm 42058/4037

PACKAGE LEAFLET FOR: Dopram-V Drops 20 mg/ml oral drops solutions

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 Drops 20 mg/ml oral drops solution

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

Dopram-V Drops are presented in dropper bottles containing 5 ml.

Each 1 ml contains:

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

Excipients: Chlorobutanol hemihydrate 5 mg (antimicrobial preservative).

4. INDICATION(S)

Respiratory stimulant.

For neonate (new born) dogs, cats, calves and lambs:

To initiate or stimulate respiration following dystocia (difficult birth) or Caesarean section.

5. CONTRAINDICATIONS

-

6. ADVERSE REACTIONS

-

7. TARGET SPECIES

Neonate dogs, cats, calves and lambs

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

ENSURE AIRWAY IS NOT OBSTRUCTED BEFORE USE.
FOR SUBLINGUAL (TOPICAL) USE ONLY

Recommended doses are indicated in the table below:

Puppies	2-10 drops	1-5 mg
Kittens	2-4 drops	1-2 mg
Lambs	10-20 drops	5-10 mg
Calves	80-200 drops (2-5 ml)	40-100 mg

The action of Dopram-V Drops is rapid, usually beginning in a few seconds. The duration and intensity of response depends on the dose and the condition of the animal at the time it is administered.

9. ADVICE ON CORRECT ADMINISTRATION

Administer on the ventral (underside) surface of the tongue. The dose should be adjusted to meet the requirements of the situation, in particular the size of the neonate and the degree of respiratory depression. Repeated doses should not be given until the effects of the first dose have passed and the condition of the animal requires it.

10. WITHDRAWAL PERIOD(S)

Dopram-V Drops are contra-indicated for use in food producing animals with the exception of neonatal calves and lambs. In 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.

11. SPECIAL STORAGE PRECAUTIONS

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

The cap should be replaced on the bottle immediately after use.

Store in a refrigerator (+2°C to +8°C).

Protect from frost. Protect from light.

Keep the container in the outer carton.

12. SPECIAL WARNING(S)

Keep out of the sight and reach of children.

Do not exceed the recommended dosage.

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

Avoid 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.

For animal treatment only

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

Unused product or waste materials should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2017

15. OTHER INFORMATION

Package quantities

5 ml and 25 ml plastic dropper bottles. Not all pack sizes may be marketed.

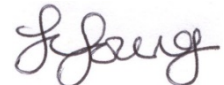
Dopram-V is also available in 20 ml vials for injection.

POM-VPS

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Vm 42058/4037

Approved: 13/04/2017

A handwritten signature in dark ink, appearing to be 'J. J. J.', is written below the approval date.