SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
   Dopram V Drops 20mg/ml Oral Drops, Solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
   Active substance:
   Doxapram Hydrochloride 20mg/ml (equivalent to 17.5mg doxapram)

   Excipient:
   Chlorobutanol 5.0mg/ml (Antimicrobial preservative)
   For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
   Oral drops, solution.
   Clear, colourless aqueous solution

4. CLINICAL PARTICULARS
   4.1 Target species
   Dogs, cats, calves and lambs.

   4.2 Indications for use, specifying the target species
   To initiate or stimulate respiration in neonatal dogs, cats, calves and lambs, following dystocia or caesarean section.

   4.3 Contraindications
   None.

   4.4 Special warnings for each target species
   Do not exceed the recommended dosages.
4.5 Special precautions for use

i) Special precautions for use in animals

A patent airway is essential.

Repeated dosage should not be given until the effects of the first dose have passed and the condition of the patient requires it.

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

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

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.

4.6 Adverse reactions (frequency and seriousness)

No significant side effects at recommended dosage.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

Not applicable for the recommended use in neonates.

4.9 Amounts to be administered and administration route

For sublingual use only.

Administer on the ventral (underside) surface of the tongue at the following doses:

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

The dosage should be adjusted to meet the requirements of the situation, in particular the size of the neonate and degree of respiratory depression. The action of the drops is rapid, usually beginning in a few seconds. The
duration and intensity of response depends upon the dose and the condition of
the animal at the time it is administered.

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

See special precautions for use (section 4.5).

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 to respirogenic dose was calculated to be 38:1.

4.11 Withdrawal periods

For 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.

5. **PHARMACOLOGICAL PROPERTIES**

**ATCvet Code:** QR07AB01

i) Pharmacodynamics

Doxapram hydrochloride is a potent respiratory stimulant, which acts specifically
on the respiratory centre. The respiratory stimulant actions are accompanied by
moderate vasopressor effects.

ii) Pharmacokinetics

The metabolism of doxapram has been studied in the rat, 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 a sublingual dose of doxapram are terminated within
15-20 minutes following administration.

6. **PHARMACEUTICAL PARTICULARS**

6.1 List of excipients

Chlorobutanol
Sodium hydroxide
Water purified

6.2 Incompatibilities

Do not mix the product with other medicinal products/solutions.
6.3 **Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years  
Shelf life after first opening the immediate packaging: 28 days.

6.4 **Special precautions for storage**

Store at +2 - +8 °C. Do not freeze. Protect from light. Protect from freezing.  
Following withdrawal of the first dose use the product within 28 days.

6.5 **Nature and composition of immediate packaging**

Dopram-V Drops is available in 5 ml and 25 ml clear, colourless, low density polyethylene bottle with integral dropper insert.  
Closure: Blue opaque, high density polyethylene screw cap.  
Not all pack sizes may be marketed.

6.6 **Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. **MARKETING AUTHORISATION HOLDER**

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

8. **MARKETING AUTHORISATION NUMBER**

Vm: 42058/4037

9. **DATE OF FIRST AUTHORISATION**

Date: 01 October 1991

10. **DATE OF REVISION OF THE TEXT**

Date: July 2014

APPROVED T. NASH 29/07/14