

## **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