Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Dopram - V Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active Substance

Doxapram Hydrochloride 20 mg

Excipients

Chlorobutanol Hemihydrate 5 mg (antimicrobial preservative)

3 PHARMACEUTICAL FORM

Oral drops, solution.

A clear colourless 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

Do not use in food producing animals with the exception of neonatal calves and lambs.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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.

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.

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 Period(s)

Neonatal calves and lambs:

Meat and offal: 28 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: respiratory stimulants

ATC vet code: QR07AB01

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

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 Hemihydrate
Purified Water

6.2 Incompatibilities

The drops should not be mixed with other 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°C to + 8°C. Protect from light.

Keep the container in the outer carton.

6.5 Nature and composition of immediate packaging

The product is available in 5ml polyethylene dropper bottles with screw caps.
Contents: Clear colourless aqueous solution.
Closure: Blue opaque HDPE cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10438/024/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 2000

Date of last renewal: 30th September 2010

10 DATE OF REVISION OF THE TEXT

July 2014