1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROPOFLO PLUS 10 mg/ml, Emulsion for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Propofol 10 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl Alcohol (E1519)	20 mg
Soya-bean oil, refined	
Purified egg phosphatides (egg lecithin)	
Glycerol	
Oleic acid	
Sodium hydroxide (for pH adjustment)	
Water for injections	

A white emulsion with no evidence of phase separation.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for therapeutic use in dogs and cats as a short acting, intravenous general anaesthetic with a short recovery period:

For procedures of short duration, lasting up to approximately 5 minutes.

For induction of general anaesthesia where maintenance is provided by inhalation anaesthetic agents.

For induction and short-term maintenance of general anaesthesia by administration of incremental doses of the product to effect for approximately half an hour (30 minutes), not to exceed the total dose stated in section 3.3.

3.3 Contraindications

Do not use for prolonged infusion (see section 3.5).

Do not exceed a total dose in one anaesthetic episode of 24 mg/kg (2.4 ml/kg) of propofol in cats or dogs.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

This product is a stable emulsion; discard the vial if phase separation is observed. Shake the vial gently but thoroughly before withdrawing a dose.

If this product is injected very slowly, an inadequate plane of anaesthesia can occur.

3.5 Special precautions for use

Special precautions for safe use in the target species:
During induction of anaesthesia in any species, mild hypotension and transient apnoea, similar to effects with other intravenous anaesthetic agents, may occur. Apnoea is most likely to occur within the first 5 minutes of administration of the product and must be treated with oxygen and artificial ventilation. **Whenever the product is used, facilities for the maintenance of a patent airway, artificial ventilation and oxygen supplementation must be immediately available.**

As with other intravenous anaesthetic agents, caution should be exercised in dogs and cats with cardiac, respiratory, renal or hepatic impairment, or in hypovolaemic or debilitated animals.

The safety of this product has not been established in dogs or cats younger than 5 months and should be used in these animals only according to the benefit-risk assessment by the responsible veterinarian

This product should not be used for induction and maintenance of general anaesthesia by incremental doses that would exceed total dose limits specified in section 3.3 (Contraindications), due to the potential for toxic effects caused by the preservative, benzyl alcohol (see section 3.10).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Propofol is a potent general anaesthetic drug and particular care should be taken to avoid accidental self-injection. Use aseptic techniques when administering the product. A guarded needle should preferably be used until the moment of injection..

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician, but DO NOT DRIVE as sedation may occur.

This product may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to propofol, benzyl alcohol, soya or egg, should avoid contact with the veterinary medicinal product.

In case of accidental spillage onto skin or in the eyes, wash off immediately with plenty of water.

To the physician: do not leave the patient unattended. Maintain airways and give symptomatic and supportive treatment.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs and cats:

Uncommon (1 to 10 animals / 1,000 animals treated):	Cardiac depression[1] Respiratory depression[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction[6] Excitation[1,3], Behavioural disorder[3,8,9] Hypotension[1,2] Emesis[3], Retching[8] Heinz body anaemia[4] Nystagmus[5], Opisthotonos[5], Paddling[5], Recovery prolonged[4,5], Twitching[1,3,5] Apnoea[1,2], Panting[7], Sneezing[8]

[1] During induction
[2] Mild
[3] During recovery.
[4] Limiting repeated anaesthesia to intervals of more than 48 hours will reduce the likelihood.
[5] Associated with the excitation phase.
[6] If inadvertently administered perivascular.
[7] If present before induction, it may continue throughout the subsequent periods of anaesthesia and recovery.
[8] Observed in cats only.
[9] Observed as paw/face licking.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of this product in foetuses/neonates and during pregnancy/lactation has not been established. In humans parenterally administered benzyl alcohol has been associated with a fatal toxic syndrome in preterm neonates.

Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Propofol has been used after premedication with commonly used premedicants, e.g. atropine, acepromazine, diazepam, α-2 adrenoceptor agents, prior to maintenance with inhalational agents, e.g. halothane, nitrous oxide, sevoflurane, isoflurane and prior to administration of analgesic agents, e.g. pethidine, buprenorphine. No pharmacological incompatibility has been encountered.

The concurrent use of sedative or analgesic drugs is likely to reduce the dose of the veterinary medicinal product required to produce and maintain anaesthesia. See section 3.9.

3.9 Administration routes and dosage

The veterinary medicinal product is a sterile product for intravenous administration.

General handling procedures:
Prior to use, the product should be inspected visually for absence of particulate matter and discolouration and discarded if present.
Shake the vial gently but thoroughly before opening. See sections 3.4 and 5.3.

Dosage for Induction:

The induction dose is calculated according to bodyweight and may be administered to effect over a period of 10-40 seconds. See section 3.4. The use of preanaesthetic drugs may markedly reduce propofol requirements. As with other sedative hypnotic agents, the amount of opioid, α-2 agonist and/or benzodiazepine premedication will influence the response of the patient to an induction dose of the product.

Where animals have been premedicated with an α-2 agonist such as medetomidine, the dose of propofol (as with any other intravenous anaesthetic agent) should be reduced by up to 85% (e.g. from 6.5 mg/kg for un-premedicated dogs to 1.0 mg/kg for dogs premedicated with an α-2 agonist).

The average induction dose for dogs and cats, either un-premedicated or when premedicated with a non-α-2 agonist tranquilliser such as acepromazine, is given in the following table.

These doses are for guidance only; the actual dose should be based on the response of the particular animal. See section 3.3.

	Dose mg/kg bodyweight	**Dose volume ml/kg bodyweight**
DOGS		
Un-premedicated	6.5 mg/kg	0.65 ml/kg
Premedicated		
- with non-α-2 agonist	4.0 mg/kg	0.40 ml/kg
- with an α-2 agonist	1.0 mg/kg	0.10 ml/kg
CATS		
Un-premedicated	8.0 mg/kg	0.80 ml/kg
Premedicated		
- with non-α-2 agonist	6.0 mg/kg	0.60 ml/kg
- with an α-2 agonist	1.2 mg/kg	0.12 ml/kg

Dosage for Maintenance:
When anaesthesia is maintained by incremental injections, the dose rate will vary between animals. Administer incremental doses of the product to effect by giving small doses of around 0.1 ml/kg bodyweight (1.0 mg/kg bodyweight) of the induction dose when anaesthesia becomes too light. These doses may be repeated as often as required, allowing 20 - 30 seconds to assess the effect before further increments are given. Experience has shown that doses of approximately 1.25 - 2.5 mg (0.125 - 0.25 ml) per kg bodyweight sustain anaesthesia for periods of up to 5 minutes.

Continuous and prolonged exposure (greater than 30 minutes) may lead to slower recovery, particularly in cats. See section 3.3 and 3.10.

Maintenance by inhalation agents:
When inhalation agents are used to maintain general anaesthesia, experience indicates that it may be necessary to use a higher initial concentration of the inhalant anaesthetic than is usually required following induction with barbiturate agents such as thiopentone.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Accidental overdosage is likely to cause cardio-respiratory depression. Overdose is likely to cause apnoea. In cases of respiratory depression, stop drug administration, establish a patent airway, and initiate assisted or controlled ventilation with pure oxygen. Cardiovascular depression should be treated with plasma expanders, pressor agents, anti-arrhythmic agents or other techniques as appropriate for the observed abnormality.

Propofol:

A single dose of 19.5 mg/kg (1.95 ml/kg) in dogs and bolus and intermittent doses totalling 24 mg/kg (2.4 ml/kg) in cats did not cause harm. Bolus and intermittent doses totalling 38.6 mg/kg (3.9 ml/kg) produced paraesthesia in one of four cats and prolonged recovery in all four cats treated.

Benzyl Alcohol (preservative):
Benzyl alcohol toxicity may lead to prolonged recovery and hyperkinesia in cats, and neurological signs such as tremors in dogs and fatalities in both species. There is no specific antidote; supportive treatment should be given.

In dogs, lethal doses of benzyl alcohol could result from administration of the maximum total dose of propofol stated in section 3.3, every hour for 9 hours, based on pharmacokinetic modelling and literature reports. In cats, lethal doses of benzyl alcohol could occur within 6.5 hours of administration, based on literature reports, direct estimation and maintenance dose rates.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN01AX10

4.2 Pharmacodynamics

Propofol (2,6-diisopropylphenol) is an intravenous sedative hypnotic agent for use in the induction and maintenance of general anaesthesia.

Propofol is a short acting anaesthetic characterised by rapid onset and short duration of anaesthesia and by rapid recovery. Propofol produces unconsciousness by its depressant action on the central nervous system.

4.3 Pharmacokinetics

Intravenous injection is followed by extensive metabolism of propofol in the liver to inactive conjugates which are excreted in the urine (major route) and faeces. Elimination from the central compartment occurs rapidly, with an initial half-life of less than 10 minutes. After this initial phase, the decrease in plasma concentration is slower.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with any other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not freeze.
Keep the vial in the outer carton.

5.4 Nature and composition of immediate packaging

Vials (Type I glass) with fluorinated polymer coated bromobutyl rubber stoppers and flip off aluminum/polypropylene seals.

Package sizes:

Carton containing 5 × 20 ml glass vials.
Carton containing 1 × 50 ml glass vial.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/056/001

8. DATE OF FIRST AUTHORISATION

27 April 2012

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

21 February 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).