SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Propofol- Lipuro 10 mg/ml emulsion for injection Braun veterinary use.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Propofol 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Soya-bean oil
Medium-chain triglycerides
Glycerol
Egg Phospholipids for Injection
Sodium oleate
Water for injections

Emulsion for injection.
White milky oil-in-water emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Dog.

3.2 Indications for use for each target species

Short -acting intravenous general anaesthetic used for:
- general anaesthesia of short duration (less than 10 minutes) for procedures such as splinter removal, radiographs, wound treatment, etc.
- induction and maintenance of long-duration general anaesthesia.
- induction of anaesthesia and later maintenance with inhalation anaesthetics (gases).

3.3 Contraindications

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

3.4 Special warnings

The duration of anaesthesia is considerably more prolonged in greyhounds than in other breed, therefore the dose should be adjusted.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The administration rate must be controlled since a too fast administration can cause apnoea and too slow it can eliminate the inductive effect. During the propofol administration facilities for the maintenance of a patent airway, artificial ventilation and enriched oxygen should be available.

Caution should be exercised in animals with cardiac, respiratory, renal or hepatic impairment or hypovolemic or debilitated dogs.

The dose should be adjusted during the administration of propofol to hypovolemic dogs because propofol deeply reduces blood pressure.

Geriatric patients are more sensitive to propofol, so doses should be adjusted carefully.

In animals with cardiomyopathies the myocardical hypoxia during induction phase can be prevented with preanaesthetical administration of oxygen during 5-7 minutes.

Propofol should be used with caution in patients with a clinical history of epilepsy, lipid metabolism disorders and pancreatitis.

The concurrent administration of propofol with vagotonic agents, may cause a deep decrease of the heart rate therefore it is recommended an administration under intensive monitoring to the animals.

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. 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.

Avoid contact with the skin and eyes as this product can cause irritation. Wash off splashes from the skin and eyes immediately with plenty of water. Seek medical advice if irritation persists.

This product may cause hypersensitivity (allergy) reactions in those that are already ensitized to propofol or other drugs, soya or egg. People with known hypersensitivity to these substances should avoid contact with the veterinary medicinal product.

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

3.6 Adverse events

Dogs

Undetermined frequency (cannot be estimated from the available data)	Injection site pain[1] Bradycardia and hypotension[2,3] Apnoea[2] Diarrhoea and vomiting[4]

[1] It may appear if the administration is too fast.
[2] They can occur during the induction phase.
[3] Dose-time dependent and generally, the apnoea period is short and reversible.
[4] It can appears during the recovery phase.

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

In teratogenesis studies performed in laboratory animals, propofol crossed the placenta remaining the embryos exposed to propofol in a dose-dependent way. The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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

3.8 Interaction with other medicinal products and other forms of interaction

The administration of cytochrome P450 inhibitors like chloramphenicol and the use of inhalation anaesthetics have important effects on pharmacokinetics and recovery from anaesthesia in dogs. For that reason, when administered together it is necessary to adjust the dose of propofol to avoid possible adverse effects.

The concurrent administration of propofol with vagotonic agents, may cause a deep decrease of the heart rate therefore it is recommended an administration under intensive monitoring to the animals.

3.9 Administration routes and dosage

Way of administration: only for intravenous use.
If propofol is injected very slowly, an inadequate plane of anaesthesia may result.
Shake the vial gently thoroughly before opening.

Induction of anaesthesia
The induction dose is computed according to the bodyweight, and may be given in full, as a single dose. Alternatively, the computed dose may be administered over a period of 10-40 seconds. The induction dose is reduced by the use of premedicants.

It should be noted that the dose rates shown are for guidance and in practice the dose rate should be based on response. The average induction dose for dogs, either unpremedicated or when premedicated with tranquilizer such as acepromazine, is indicated as follows:

		Dose rate mg/kg body weight	Dose volume
Dogs	Unpremedicated	6.5	6.5 ml/10 kg
	Premedicated	4.0	4.0 ml/10 kg

Maintenance of anaesthesia

a. Maintenance by Propofol
Anaesthesia can be maintained by administering Propofol-Lipuro 10 mg/ml either by repeat incremental injections or by continuous infusion.

- ***Incremental Injection (bolus)***

Where anaesthesia is maintained by incremental injections, the dose rate will vary between animals. Incremental doses should be given to effect. Experience in clinical trials has shown that dose around 1 ml per 4.0-8.0 kg bodyweight sustain (2.5-1.25 mg kg b.w.) anaesthesia for periods up to five minutes.

- ***Continuous infusion***

For continuous infusion anaesthesia in dogs premedicated e.g. acepromazine 0.05 mg/kg and atropine 0.02 mg/kg the suggested dose rate 0.4 mg/kg/min.

Propofol-Lipuro 10 mg/ml should be administered intravenously by continuous infusion either undiluted or diluted with 5% w/v glucose solution or 0.9% w/v sodium chloride solution as well as in a 0.18% w/v sodium chloride and 4% w/v glucose solution.

- Infusion of undiluted Propofol Lipuro 10 mg/ml
When administering Propofol-Lipuro 10 mg/ml by continuous infusion, it is recommended that burettes, drop counters, syringe pumps or volumetric infusion pumps, should always be used to control the infusion rates. As established for the parenteral administration of all kinds of fat emulsions, the duration of continuous infusion of Propofol-Lipuro 10 mg/ml from one infusion system must not exceed 12 hours. The infusion line and the reservoir of Propofol-Lipuro 10 mg/ml must be discarded and replaced after 12 hours at the latest. Any portion of Propofol-Lipuro 10 mg/ml remaining after the end of infusion or after replacement of the infusion system must be discarded.

- Infusion of diluted Propofol Lipuro 10 mg/ml
For administering infusion of diluted Propofol-Lipuro 10 mg/ml, burettes, drop counters, syringe pumps, or volumetric infusion pumps should always be used to control infusion rates and to avoid the risk of accidentally uncontrolled infusion of large volumes of diluted Propofol-Lipuro 10 mg/ml.

The maximum dilution must not exceed 1 part of Propofol-Lipuro 10 mg/ml with 4 parts of 5 % w/v glucose solution or 0.9 % w/v sodium chloride solution, or 0.18 % w/v sodium chloride and 4 % w/v glucose solution (minimum concentration 2 mg/ml). The mixture should be prepared aseptically immediately prior to administration and must be used within 6 hours of preparation.

Propofol-Lipuro 10 mg/ml must not be mixed with other solutions for injection or infusion. However, co-administration of Propofol-Lipuro 10 mg/ml together with 5 % w/v glucose solution or 0.9 % w/v sodium chloride solution, or 0.18 % w/v sodium chloride and 4 % w/v glucose solution via a Y-connector close to the injection site is possible.

The medicinal product contains no antimicrobial preservatives; in order to avoid infections caused by bacterial contamination the precautions before use should be taken into account. For that, before use, the neck of the ampoule or the surface of the rubber stopper of the bottle should be cleaned with medicinal alcohol (spray or swabs). After use, tapped containers must be discarded.

Propofol-Lipuro 10 mg/ml is to be drawn up aseptically into a sterile syringe or an infusion set immediately after opening the ampoule or breaking the bottle seal. Administration must be started without delay. Asepsis must be maintained for the medicinal product and the infusion equipment throughout the infusion period.
The contents of one ampoule or one bottle of Propofol-Lipuro 10 mg/ml and any syringe containing the medicinal product are for single use in one patient. Any portion of the contents remaining after use must be discarded.

b. 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, as thiopental.

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

Accidental overdosage is likely to cause cardio-respiratory depression. Treat the respiratory by artificial ventilation and oxygen. Cardiovascular depression may require administration of plasma expanders and pressor agents.

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 only by a veterinarian.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code

QN01AX10

4.2 Pharmacodynamics

Propofol (2,6-diisopropylphenol) is a short-acting intravenous general anaesthetic with a particularly rapid onset of anaesthetic effect. Propofol is characterized by a rapid induction, practically no accumulation so it provides an anaesthesia easy to adjust as well as a fast recovery.

Propofol acts by inducing depression of the inhibiting neurotransmitter GABA (gamma-aminobutyric acid receptor), which diminishes cerebral metabolic activity and lowers intracranial pressure and cerebral perfusion pressure.

4.3 Pharmacokinetics

After i.v. administration about 98 % of propofol is bound to plasma protein. Propofol is metabolised in the liver (by the specific cytochrome P450 enzyme) quickly to glucuronic metabolites and sulphate conjugates, with the formation of trace amounts of other compounds.

It is eliminated in an inactive form by the kidney (88% of the administered dose is excreted in urine as a conjugate [40%] and 4-hydroxy-propofol [60%], and a minimal amount is excreted unmodified [< 0.3%] and in faeces in a small amount.

Since propofol is metabolised in the liver and is eliminated in an inactivated form by the kidney, liver disease prolongs recovery time.

Its half-life of distribution is 2-4 minutes. The rate of elimination of propofol from plasma is superior to hepatic blood flow, suggesting the existence of sites of extrahepatic metabolism of the product in addition to hepatic metabolism. The elimination half-life is around 30 minutes.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

This medicinal product must not be mixed with other products except those mentioned in 3.9. " Administration routes and dosage ", section "Infusion of diluted Propofol-Lipuro 10 mg/ml”.

5.2 Shelf life

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

5.3 Special precautions for storage

Store below 25 ºC. Do not freeze.

5.4 Nature and composition of immediate packaging

Colourless glass ampoules of type I and colourless glass bottles of type II. The bottles are provided with bromobutyl rubber closure and aluminium caps.

Pack sizes:
Cardboard box with 5 glass ampoules of 20 ml.
Cardboard box with 1 glass bottle of 20 ml.
Cardboard box with 1 glass bottle of 50 ml.
Cardboard box with 1 glass bottle of 100 ml.
Cardboard box with 10 glass bottles of 20 ml.
Cardboard box with 10 glass bottles of 50 ml.
Cardboard box with 10 glass bottles of 100 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

B. Braun VetCare SA
Carretera de Terrassa, 121
08191 Rubí, (Barcelona). Spain

7. MARKETING AUTHORISATION NUMBER(S)

1578 ESP (Spain)
51623 (Portugal)

8. DATE OF FIRST AUTHORISATION

08 July 2004 (Spain)
03 May 2011 (Portugal)

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

DD month YYYY

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).