

PACKAGE LEAFLET

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1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance

Propofol 10 mg

Excipients

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. Target species

Dog.

4. Indications for use

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).

5. Contraindications

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

6. Special warnings

Special warnings

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

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 myocardial hypoxia during induction phase can be prevented with preanaesthetic 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 sensitised to propofol or other drugs, soya or egg. People with known hypersensitivity to these substances should avoid contact with the veterinary medicinal product.

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.

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.

Overdose:

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.

Special restrictions for use and special conditions for use:

For administration only by a veterinarian.

Major incompatibilities:

This medicinal product must not be mixed with other products except 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.

7. 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
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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 appear during the recovery phase.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

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.

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.

9. Advice on correct administration

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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Store below 25 °C. Do not freeze.

Shelf life after first opening the immediate packaging: use immediately.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

1578 ESP (Spain)

51623 (Portugal)

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.

15. Date on which the package leaflet was last revised

DD month YYYY

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

B. Braun VetCare SA

Ctra. de Terrassa, 121.

ES-08191 Rubí. (Barcelona)

Telephone: +34 93 586 62 00

Manufacturer responsible for batch release:

B. Braun Medical SA

Ctra. de Terrassa, 121.

ES-08191 Rubí. (Barcelona)

or

B. Braun Melsungen AG

Carl-Braun-Str.1.

D-34212 Melsungen

In Portugal

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder:

B. Braun Medical, Unipessoal Lda.
Est. Consiglieri Pedroso, 80
Queluz de Baixo
2730-053 Barcarena
Portugal
Telefone: +351 21 4368200