

LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard-boxes containing: 10 x 20 ml glass vials and 5 x 20 ml ampoules

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Propofol-Lipuro Vet 10 mg/ml emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml emulsion contains:

10 mg Propofol

3. PACKAGE SIZE

10 x 20 ml

5 x 20 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

Injectable anaesthetic for cats and dogs.

6. ROUTES OF ADMINISTRATION

For intravenous use.

7. WITHDRAWAL PERIODS

Not applicable.

8. EXPIRY DATE

EXP month/year

9. SPECIAL STORAGE PRECAUTIONS

Store below 25° C. Do not freeze.

Any product remaining in the container following withdrawal of the required dose should be discarded.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG

14. MARKETING AUTHORISATION NUMBERS

Vm: 03551/4001

15. BATCH NUMBER

LOT:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial 20 ml and Ampoule 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Propofol-Lipuro Vet 10 mg/ml emulsion for injection

2. QUANTITY PARTICULARS OF THE ACTIVE SUBSTANCES

Propofol 10 mg

3. BATCH NUMBER

LOT:

4. EXPIRY DATE

EXP: month/year.

Once opened use immediately.

PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Propofol-Lipuro Vet 10 mg/ml emulsion for injection

2. Composition

1 ml emulsion contains:

Active substance

Propofol 10 mg

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

3. Target species

Dogs and cats.

4. Indications for use

Injectable anaesthetic for dogs and cats.

A short acting intravenous general anaesthetic used for procedures of short duration, lasting up to five minutes.

For induction and short-term maintenance of general anaesthesia using incremental doses to effect.

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

5. Contraindications

Do not use in animals with known hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings

The veterinary medicinal product is a stable emulsion. Prior to use, the veterinary medicinal product should be inspected visually for absence of visible droplets or extraneous foreign particles or phase separation and discarded if present. Do not use if evidence of phase separation remains after gentle shaking.

If the veterinary medicinal product is injected too slowly, an adequate plane of anaesthesia may not be achieved due to failure to reach the appropriate threshold of pharmacological activity.

Special precautions for safe use in the target species

During induction of anaesthesia, mild hypotension and transient apnoea may occur. When using the veterinary medicinal product, facilities for the maintenance of a patent airway, artificial ventilation and oxygen enrichment must be available. Following induction of anaesthesia, the use of an endotracheal tube is

recommended. Increased levels of carbon dioxide in blood have been reported with increased duration of propofol anaesthesia. It is advisable to administer supplemental oxygen during maintenance of anaesthesia. In addition the need for assisted ventilation should be considered during prolonged anaesthesia.

If the veterinary medicinal product is injected too rapidly, cardiopulmonary depression may occur (apnoea, bradycardia, hypotension).

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

Propofol may increase blood glucose metabolism and insulin secretion in healthy dogs. In the absence of safety data in diabetic animals, use only after a benefit/risk assessment by the veterinarian.

Care should be taken when administering the veterinary medicinal product to patients with hypoproteinaemia, hyperlipidaemia or very thin animals since these animals may be more susceptible to adverse effects.

The safety of the veterinary medicinal product has not been established in dogs or cats younger than 4 months and should be used in these animals only according to the benefit/risk assessment by the responsible veterinarian.

It has been reported that the clearance of propofol is slower in overweight/obese animals and dogs over 8 years of age. Extra care should be taken when administering the veterinary medicinal product to these animals; in particular, a lower dose of propofol may be adequate for induction and maintenance in such cases. Sighthounds have been reported to show a slower clearance of propofol and may have a slightly longer duration of recovery from anaesthesia compared to other breeds of dog.

Propofol does not have analgesic properties, therefore supplementary analgesic agents should be provided in cases where procedures are anticipated to be painful. When propofol is used concomitantly with opioids, an anticholinergic agent (e.g. atropine) may be used in cases of bradycardia according to the benefit/risk assessment by the responsible veterinarian. See section 6 Interaction with other medicinal products and other forms of interaction.

Use aseptic techniques when administering the veterinary medicinal product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This is a potent drug: particular care should be taken to avoid accidental self-administration. Preferably use a guarded needle until the moment of injection. Ampoules, particularly, should be opened with care to avoid cutting oneself.

Wash off splashes from skin or eyes immediately

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

Advice to doctor: Do not leave the patient unattended. Maintain airways and give symptomatic and supportive treatment.

Pregnancy and lactation

The safety of the veterinary medicinal product has not been established during pregnancy (in foetuses/neonates) and during lactation. Propofol has been safely used in dogs for the induction of anaesthesia prior to delivery of puppies by caesarean section.

Only use according to the benefit-risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction

Propofol may be used in association with premedicants, e.g. atropine, glycopyrrolate, α -2 agonists (medetomidine, dexmedetomidine), acepromazine, benzodiazepines (diazepam, midazolam); inhalational agents (e.g. halothane, isoflurane, sevoflurane, enflurane and nitrous oxide); and analgesic agents such as pethidine and buprenorphine.

The veterinary medicinal product may be administered parallel to all intravenous fluids via e.g. a Y-piece positioned near the injection site.

The concurrent use of sedative or analgesic drugs is likely to reduce the dose of propofol required to induce and maintain anaesthesia.

Concomitant use of propofol and opioids may cause significant respiratory depression and a profound decrease in heart rate. In cats, concurrent use of propofol and ketamine has been reported to cause apnoea more frequently than use of propofol with other premedicants. To reduce the risk of apnoea, propofol should be administered slowly over 20–60 seconds. See also section 6 Special precautions for use in animals.

Co-administration of propofol and opioid (e.g. fentanyl, alfentanil) infusions for maintenance of general anaesthesia may result in a prolonged recovery. Cardiac arrest has been observed in dogs that received propofol followed by alfentanil. Administration of propofol with other medicinal products that are metabolised by cytochrome P450 (isoenzyme 2B11 in the dog) such as chloramphenicol, ketoconazole and loperamide) reduces propofol clearance and prolongs recovery from anaesthesia.

Overdose

Accidental overdose is likely to cause cardio-respiratory depression. In such cases, ensure the airways are open and initiate assisted or controlled ventilation with oxygen, administering pressor agents and intravenous fluids to support cardiovascular function.

Major incompatibilities

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

7. Adverse events

Dogs

Very common (>1 animal / 10 animals treated):	Apnoea (temporary cessation of breathing)
Common (1 to 10 animals / 100 animals treated):	Excitation Arrhythmia, Bradycardia (slow heart rate), Hypotension (low blood pressure), Hypertension ^a Emesis (vomiting), Hypersalivation (increased salivation), Retching Paddling, Myoclonus (involuntary movements), Nystagmus (involuntary eye movement), Opisthotonus (hyperextension of head, neck and spine), Recovery prolonged ^b Sneezing Face/nose rubbing
Uncommon (1 to 10 animals / 1 000 animals treated):	Injection site pain ^c Hyperglycemia (high blood glucose levels)

^a If propofol is used without premedication as a sole agent in induction of anaesthesia, a short transient increase of arterial blood pressure can be observed.

^b Slow recovery.

^cAfter intravenous administration.

Cats

Very common (>1 animal / 10 animals treated):	Apnoea (temporary cessation of breathing)
Common (1 to 10 animals / 100 animals treated):	Excitation Arrhythmia, Bradycardia (slow heart rate), Hypotension (low blood pressure) Emesis (vomiting), Hypersalivation (increased salivation), Retching Paddling, Myoclonus (involuntary movements), Nystagmus (involuntary eye movement), Opisthotonos (hyperextension of head, neck and spine), Recovery prolonged Sneezing Face/nose rubbing
Uncommon:	Injection site pain ^a Diarrhoea ^b Facial oedema ^{b,c} (swelling) Hyperglycemia (high blood glucose levels), Heinz body anaemia ^b Anorexiab (loss of appetite)

^a After intravenous administration.

^b In cats undergoing repeated anaesthesia. Limiting repeated anaesthesia to intervals of more than 48 hours will reduce the likelihood. The effects are generally transient and resolve on their own.

^c Mild facial oedema.

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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Administration: By intravenous injection. Before opening the container, the product should be inspected visually for the absence of visible droplets or extraneous foreign particles and discarded if present. The container should be shaken gently but thoroughly before use. The emulsion should not be mixed with other therapeutic agents or infusion fluids prior to administration. The product should be used immediately after opening.

Induction:

The induction dose is computed according to bodyweight and may be administered to effect over a period of 10 - 40 seconds. Alternatively, the computed dose may be given in full as a single bolus.

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 and cats, either unpremedicated or when premedicated with non alpha-2-agonist tranquilizer such as acepromazine, is indicated as follows:

	Dose rate mg/kg bodyweight	Dose volume ml/kg bodyweight
Dogs		
Unpremedicated	6.5	6.5 ml/10 kg
Premedicated	4.0	4.0 ml/10 kg
Cats		
Unpremedicated	8.0	2.0 ml/2.5 kg
Premedicated	6.0	1.5 ml/2.5 kg

Maintenance by Propofol-Lipuro Vet 10 mg/ml:

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 of around 1 ml per 4.0-8.0 kg bodyweight sustain anaesthesia for periods up to five minutes.

Maintenance by inhalation agents:

Where inhalation agents are used to maintain general anaesthesia, clinical experience indicates that there may be need to use a higher initial concentration of

the inhalant agent than is normally the case following induction with barbiturate agents such as thiopentone.

Continuous and prolonged exposure may lead to slower recovery, particularly in cats.

9. Advice on correct administration

Use aseptic techniques when administering the product as it does not contain an antimicrobial preservative.

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. Any product remaining in the container following withdrawal of the required dose should be discarded. Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of the 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 03551/4001

Package quantities:

Ampoules of 20 ml in boxes of 5.

Glass vials of 20 ml sealed with rubber stoppers in boxes of 10.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

B. Braun Melsungen AG
Carl-Braun-Strasse 1
34212 Melsungen
Germany

Local representatives and contact details to report suspected adverse reactions:

B. Braun Medical Ltd
Brookdale Road
Thorncliffe Park Estate
Sheffield
S35 2PW
Email: medinfo.bbmuk@bbraun.com
Tel: 0800 2980299

17. Other information

Propofol is a substituted phenol which, when given by intravenous injection, is a short acting anaesthetic with a rapid rate of onset. Recovery from anaesthesia is usually rapid. After a single bolus dose, blood level profiles are characterised by a rapid distribution phase and a rapid elimination phase. No accumulation of blood levels has been observed after multiple daily dosing. Propofol is metabolised by the liver. Urinary excretion is the major route of elimination of metabolites from the body.

POM-V

To be supplied only on veterinary prescription.

Gavin Hall

Approved 22 February 2026