LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard-boxes containing glass vials: 10 x 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Propofol-Lipuro Vet 10 mg/ml
Emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml emulsion contains:
10 mg Propofol
1 vial with 20 ml contains 200 mg Propofol.
Soya-bean oil, medium-chain triglycerides, glycerol, egg lecithin, sodium oleate, water for injections.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

10 x 20 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

Injectable anaesthetic for cats and dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use. See package leaflet for dosage, administration details, contraindications/warnings and disposal.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP month/year
For single use only. Any product remaining in the container following withdrawal of the required dose should be discarded.

11. SPECIAL STORAGE CONDITIONS

Store below 25° C. Do not freeze. Shake well before use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

UK blue box requirement:

POM-V

To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm: 03551/4001

17. MANUFACTURER'S BATCH NUMBER

LOT:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Propofol-Lipuro Vet 10 mg/ml
Emulsion for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE

1 ml emulsion contains:
Propofol 10 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

200 mg/ 20 ml

4. ROUTE(S) OF ADMINISTRATION

For intravenous use

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

LOT:

7. EXPIRY DATE

EXP: month/year.

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

UK blue box requirement:

POM-V

To be supplied only on veterinary prescription
Vm 03551/4001

PACKAGE LEAFLET

PACKAGE LEAFLET

Propofol-Lipuro Vet 10 mg/ml
emulsion for injection

1. MARKETING AUTHORISATION HOLDER AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Marketing authorisation holder and manufacturer responsible forbatch release:

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

Postal Address:
B. Braun Melsungen AG
34209 Melsungen - Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Propofol-Lipuro Vet 10 mg/ml
emulsion for injection

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Propofol-Lipuro Vet 10 mg/ml is a white, aqueous, isotonic emulsion for intravenous injection
1 ml emulsion contains:
Active substance
Propofol 10 mg
Excipients
Soya-bean oil
Medium-chain triglycerides
Glycerol
Egg lecithin
Sodium oleate
Water for injections

4. INDICATIONS

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. ADVERSE REACTIONS

Side-effects during induction, maintenance and recovery are uncommon. Induction is generally smooth with minimal evidence of excitation. During the recovery phase, vomiting and evidence of excitation have been observed in a small proportion of animals.

In clinical trials in cats and dogs, transient apnoea during induction has been observed frequently. In cats, sneezing, occasional retching and a paw/face licking characteristic during recovery have been observed in a small proportion of cases.
If panting is evident before induction, it may continue throughout the subsequent periods of anaesthesia and recovery.
Inadvertent perivascular administration rarely causes local tissue reactions.
Repeated anaesthesia with propofol in cats may cause oxidative injury and Heinz body formation. Recovery may also become prolonged. Limiting repeated anaesthesia to intervals of more than 48 hours will reduce the likelihood. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE 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:

I 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.

II

III 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 PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Store below 25 ºC. 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 WARNINGS

Special warnings for each target species

The product is a stable emulsion; discard the container if phase separation is observed.

If injected slowly, an inadequate plane of anaesthesia can occur.

Special precautions for use in animals

During induction of anaesthesia, mild hypotension and transient apnoea, similar to effects with other intravenous anaesthetic agents, may occur.

When using Propofol-Lipuro Vet 10 mg/ml, facilities for the maintenance of a patent airway should be 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.

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 the skin and eyes immediately.

In the event of accidental self-administration, seek urgent medical attention and show the label.

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

Use during pregnancy, lactation, or lay
The safety of propofol in fetuses/neonates and during lactation has not been established. Propofol has not been used in cats and dogs where the pregnancy is to be maintained, but has been used successfully for induction prior to Caesarean section.

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

Interaction with other medicinal products and other forms of interaction
Propofol has been used in association with commonly used premedicants, e.g. atropine, acepromazine, diazepam; inhalational agents, e.g. halothane, nitrous oxide, enflurane; and analgesic agents, e.g. pethidine, buprenorphine. No pharmacological incompatibility has been encountered.

Overdose
Accidental overdosage is likely to cause cardio-respiratory depression. Respiratory depression should be treated by artificial ventilation with oxygen. Cardiovascular depression requires the use of plasma expanders and pressor agents.

Incompatibilities

In the absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicinal products or infusion fluids prior to administration.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

Please handle and dispose of all used containers, syringes and needles carefully.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

06/2015

15. 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.

Presentation

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.

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

Vm 03551/4001

Approved: 19 September 2017