PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton (20 ml, 5 x 20 ml, 50 ml, 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Propomitor 10 mg/ml emulsion for injection/infusion

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains: propofol 10 mg

3. PACKAGE SIZE

1x20 ml
5x20 ml
1x50 ml
1x100 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

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

Orion Corporation

14. MARKETING AUTHORISATION NUMBERS

Vm 06043/3000

15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Propomitor 10 mg/ml emulsion for injection/infusion

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains: propofol 10 mg

3. TARGET SPECIES

Dogs and cats.

4. ROUTES OF ADMINISTARTION

Intravenous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp.
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation

9. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label (20 ml, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Propomitor 10 mg/ml

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Propofol 10 mg/ml

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.

Once broached use immediately.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Propomitor10 mg/ml emulsion for injection/infusion for dogs and cats

2. Composition

Active substance:
Propofol 10 mg/ml

Excipients:
Soya-bean oil, refined 100 mg/ml

This veterinary medicinal product is a white or almost white, homogenous emulsion for injection/infusion.

3. Target species

Dogs and cats.

4. Indications for use

- general anaesthesia for brief procedures lasting up to five minutes.
- induction and maintenance of general anaesthesia by administration of incremental doses to effect or as a constant rate infusion (CRI).
- induction of general anaesthesia, where maintenance is provided by inhalation anaesthetic agents.

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 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 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:

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**.

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

Avoid contact with the skin and eyes as the veterinary medicinal product can cause irritation.

Wash off splashes from skin or eyes immediately with plenty of fresh water. If irritation persists, seek medical advice and show the package leaflet/label to the physician.

To the physician:
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. Propofol crosses through the placenta and the foetus blood-brain barrier, thus during the period of brain development it may adversely affect the neurological development in foetuses and neonates. Owing to the risk of neonatal death, the use of propofol for the maintenance of anaesthesia during caesarean section is not recommended.

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

Interaction 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 veterinary medicinal product can be diluted with 5% glucose infusion solution. Compatibility studies with other infusion solutions (e.g. NaCl or lactated Ringer’s solution) have not been conducted with this veterinary medicinal product.

The concurrent use of sedative or analgesic drugs is likely to reduce the dose of propofol required to induce and maintain anaesthesia. See section 8.

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 safe use in the target species.

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 (symptoms, emergency procedures, antidotes):
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. In dogs, bolus doses greater than 10 mg/kg may cause cyanosis. Mydriasis may also be observed. Cyanosis and mydriasis serve as an indication that supplemental oxygen is necessary. Death has been reported at bolus doses of 19.5 mg/kg in cats and 20 mg/kg in dogs.

Major incompatibilities:
The veterinary medicinal product can be diluted with 5% glucose infusion solution. Compatibility studies with other infusion solutions (e.g. NaCl or lactated Ringer's solution) have not been conducted with this veterinary medicinal product.

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.

[c]After 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 (1 to 10 animals / 1 000 animals treated):	Injection site pain[a] Diarrhoea[b] Facial oedema[b,c] (swelling) Hyperglycemia (high blood glucose levels), Heinz body anaemia[b] Anorexia[b] (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 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 (https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine).
e-mail: adverse.events@vmd.gov.uk

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

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

Dose requirements can vary significantly between individual animals and are influenced by a range of factors (please refer to section 6 Special precautions for safe use in the target species, and section 6 Interaction with other medicinal products and other forms of interaction). In particular, the use of pre-anaesthetic drugs (premedication) may markedly reduce propofol requirements dependent on the type and dose of pre-anaesthetic drugs used.

The dose to be administered should be estimated based on average dose requirements in preparation for anaesthesia. The actual dose requirements of an individual animal may be significantly lower or higher than the average dose.

Induction
The induction dose of the veterinary medicinal product presented in the table below is based on data taken from controlled laboratory and field studies and is the average amount of drug required for dogs or cats to be successfully induced for anaesthesia. The actual dose administered must be based on the individual response of each animal.

DOGS	**Guide dose mg/kg bodyweight**	**Dose volume ml/kg bodyweight**
Unpremedicated	6.5	0.65
Premedicated*		
alpha-2 agonist	3.0	0.30
acepromazine-based	4.5	0.45
CATS		
Unpremedicated	8.0	0.8
Premedicated*		
alpha-2 agonist	2.0	0.2
acepromazine-based	6.0	0.6

*Induction doses significantly below the average dose may be effective after premedication with an alpha-2 adrenoceptor based protocol in some animals.

When propofol is used in combination with e.g. ketamine, fentanyl or benzodiazepines for induction of anaesthesia (so called co-induction), the total dose of propofol can be further reduced.

The dosing syringe should be prepared based on the dose volume of veterinary medicinal product shown above, calculated based on bodyweight. The dose should be administered slowly to limit incidence and duration of apnoea and administration

should continue until the clinician is satisfied that the depth of anaesthesia is sufficient for endotracheal intubation or the planned procedure. As a guide the veterinary medicinal product should be administered over a period of 20–60 seconds.

Maintenance

Repeat bolus injections
Where anaesthesia is maintained by incremental injections of the veterinary medicinal product, the dose rate and duration of effect will vary between animals. The incremental dose required to maintain anaesthesia is typically lower in premedicated animals compared with unpremedicated animals.

An incremental dose of approximately 1 mg/kg (0.1 ml/kg) in dogs and 2 mg/kg (0.2 ml/kg) in cats can be administered when anaesthesia becomes too light. This dose can be repeated as required to maintain an appropriate depth of anaesthesia, allowing 20–30 seconds between each dose to assess the effect. Each incremental dose should be administered slowly to effect.

Constant rate infusion
When anaesthesia is maintained by a constant rate infusion (CRI) of propofol, the dose is 0.2–0.4 mg/kg/min in dogs. The actual dose administered must be based on the individual response of each animal and may be increased up to 0.6 mg/kg/min for short periods. In cats, the maintenance dose is 0.1–0.3 mg/kg/min, and should be adapted to the individual response. CRI anaesthesia lasting up to 2 hours with the dose 0.4 mg/kg/min in dogs and 0.2 mg/kg/min in cats has been reported to be well tolerated. In addition, infusion rate may be increased or decreased by 0.025–0.1 mg/kg/min increments in dogs, or 0.01–0.025 mg/kg/min in cats at 5–10 min intervals to adapt the anaesthetic plane.

Continuous and prolonged exposure (greater than 30 minutes) may lead to slower recovery, especially in cats.

Maintenance of anaesthesia by inhalation agents
Where inhalation agents are used to maintain general anaesthesia, it may be necessary to use a higher initial concentration of the inhalation anaesthetic than is normally the case following induction with barbiturate agents.

Please refer also to section 6 Special precautions for safe use in the target species.

9. Advice on correct administration

Shake gently prior to use.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Shelf life after first opening the container: use immediately.

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

12. Special precautions for the disposal

Medicines should not be disposed of via wastewater or household waste. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. 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 06043/3000

Type I clear glass vial (20, 50 and 100 ml) with a grey, siliconised bromobutyl rubber stopper and an aluminium crimp.

Pack sizes: 1x20 ml, 5x20 ml, 1x50 ml, 1x100 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

October 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer responsible for batch release:
Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Orion Corporation Orion Pharma
Joensuunkatu 7
FI-24100 Salo
Finland

Local representatives and contact details to report suspected adverse reactions:
Animalcare Ltd.
Moorside, Monks Cross
York YO32 9LB
United Kingdom
Tel: +44 (0)330 8189 717
E-mail: animalcare@animalcare.co.uk

Approved 19 March 2024