

PARTICULARS TO APPEAR ON THE OUTER PACKAGE { Carton box }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Propofol 10 mg/ml emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Propofol 10 mg

3. PACKAGE SIZE

5 x 20 ml

1 x 50 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intravenous use only.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

The veterinary medicinal product should be used immediately after opening the vial.
Product remaining in the container 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

Axience

14. MARKETING AUTHORISATION NUMBER

Vm 57179/4000

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS { Type I glass vials (20 and 50 ml)}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proposure

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains 10 mg of propofol

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Propofol 10 mg/ml emulsion for injection for dogs and cats

2. Composition

Each ml contains:

Active substance:

Propofol 10 mg

White or almost white, homogenous emulsion for injection.

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.

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.

Do not use if evidence of phase separation remains after gentle shaking.

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.

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.

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

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. It is advisable to administer supplemental oxygen during maintenance of anaesthesia.

Caution should be exercised in dogs and cats with cardiac, respiratory, renal or hepatic impairment, in hypovolaemic, emaciated, old or debilitated animals.

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 "Interaction with other medicinal products and other forms of interaction".

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.

Propofol does not have analgesic properties, therefore supplementary analgesic agents should be provided in cases where procedures are anticipated to be painful. It has been reported that clearance of propofol is slower and incidence of apnoea is greater in dogs over 8 years of age than in younger animals. Extra care should be taken when administering the veterinary medicinal product to these animals, for example, a lower dose of propofol may be adequate for induction 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.

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

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 to the physician, **but DO NOT DRIVE as sedation may occur.**

People with known hypersensitivity to propofol or any of the excipients should avoid contact with the veterinary medicinal product.

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

Wash splashes from skin or eyes immediately with plenty of fresh water. Seek medical advice if irritation persists.

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

Pregnancy and lactation:

The safety of this veterinary medicinal product in foetuses/neonates and during lactation has not been established.

Successful use of the veterinary medicinal product in dogs for induction prior to Caesarean section has been reported.

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 concurrent use of sedative or analgesic drugs is likely to reduce the dose of propofol required to induce and maintain anaesthesia. See section Dosage for each species, routes and method of administration.

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 60 seconds. See also section "Special precautions for use in animals".

The veterinary medicinal product may be administered at the same time as glucose, sodium chloride and glucose+sodium chloride solutions.

The veterinary medicinal product may be mixed with glucose infusion solutions or saline solution.

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:

Do not mix with other veterinary medicinal products, with the exception of glucose infusion solutions or saline infusions.

7. Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Hypotension (mild) ¹ , Apnoea (transient) ¹
Common (1 to 10 animals / 100 animals treated):	Excitation ¹ (paddling, myoclonus, nystagmus, opisthotonus)
Rare (1 to 10 animals / 10,000 animals treated):	Vomiting ² Excitation ²

¹During the induction phase of anaesthesia

²During the recovery phase

Cats:

Very common (>1 animal / 10 animals treated):	Hypotension (mild) ¹ , Apnoea (transient) ¹
Common (1 to 10 animals / 100 animals treated):	Excitation ¹ (paddling, myoclonus, nystagmus, opisthotonus)
Uncommon (1 to 10 animals / 1,000 animals treated):	Sneezing ² Licking (of face and paws) ² Retching ² , diarrhoea ³ Heinz body anaemia ^{3,4} Anorexia ³ , Recovery prolonged ³ Facial oedema (mild) ³
Rare (1 to 10 animals / 10,000 animals treated):	Vomiting ² Excitation ²

¹During the induction phase of anaesthesia

²During the recovery phase

³In case of repeated anaesthesia with propofol, due to enhanced susceptibility of cats. This risk can be reduced by limiting repeated anaesthesia to intervals of more than 48 hours

⁴Oxydative injury and Heinz body production

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 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

For intravenous use only.

Shake gently prior to use.

Dose requirements can vary significantly between individual animals and influenced by a range of factors (please refer to 'Special precautions for use in animals' and '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 of anaesthesia

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 and cats to be successfully induced for anaesthesia.

The actual dose administered must be based and titrated on the individual clinical response of each animal.

	Guide Dose mg/kg bodyweight	Dose volume ml/kg bodyweight
DOGS		
Unpremedicated	6.5	0.65
<u>Premedicated*</u>		
alpha-2 agonist	3.0	0.30
acepromazine-based	4.5	0.45

CATS		
Unpremedicated	8.0	0.8
<u>Premedicated*</u>		
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.

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 effect and administration should continue until the clinician is satisfied that the depth of anaesthesia is sufficient for endotracheal intubation. As a guide the veterinary medicinal product should be administered over a period of 10-40 seconds.

Maintenance

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 0.15 ml/kg (1.5 mg/kg b.w.) in dogs and of approximately 0.2 ml/kg (2.0 mg/kg b.w.) 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.

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

Maintenance of anesthesia 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.

9. Advice on correct administration

The veterinary medicinal product is a sterile product for intravenous administration. Shake gently prior to use.

The veterinary medicinal product is to be drawn up aseptically into a sterile syringe immediately after opening the ampoule or breaking the bottle seal. Administration must be started without delay.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.

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

The veterinary medicinal product should be used immediately after opening the vial. Product remaining in the container should be discarded.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater .

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 NUMBER AND PACK SIZES

Vm 57179/4000

Box containing five 20 ml vials

Box containing one 50 ml vial

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:

Axience

Tour Essor

14 Rue Scandicci

93500 Pantin

France

Manufacturer responsible for batch release:
CORDEN PHARMA S.p.A.
Viale dell'Industria 3
Caponago (MB)
Italy

Local representatives and contact details to report suspected adverse reactions:
DUGV (UK) Ltd
Union House
111 New Union Street
Coventry
Warwickshire
CV1 2NT

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

17. Other information

POM-V

Gavin Hall

Approved 30 September 2025