1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proposure 10 mg/ml emulsion for injection for dogs and cats.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Propofol 10 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Egg phospholipids	
Glycerol	
Soya-bean oil refined	
Sodium hydroxide (for pH adjustment)	
Water for injections	

White or almost white, homogenous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats

3.2 Indications for use for each target species

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.

3.3 Contraindications

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

3.4 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.

3.5 Special precautions for use

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 3.8.
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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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]

[1]During the induction phase of anaesthesia
[2]During 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]

[1]During the induction phase of anaesthesia
[2]During the recovery phase
[3]In 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
[4]Oxydative injury and Heinz body production

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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 3.9.

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 3.5.

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.

3.9 Administration routes and dosage

For intravenous use only.
Shake gently prior to use.

Dose requirements can vary significantly between individual animals and are influenced by a range of factors (please refer to section 3.5 Special precautions for safe use in the target species, and section 3.8 Interactions 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.**

<u>Induction</u>

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 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
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.

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.

Please refer also to Section 3.5 Special precautions for safe use in the target species.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal period

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:: QN01AX10.

4.2 Pharmacodynamics

Propofol is a short-acting, intravenous general anaesthetic, characterised by rapid onset, a short duration of anaesthesia and by rapid recovery. Propofol produces unconsciousness by depressing the central nervous system.

The depressant effects of propofol are primarily mediated through potentiation of postsynaptic $GABA_A$ receptors in the central nervous system. However, the glutaminergic and noradrenergic neurotransmitter systems are also thought to have a role in mediating the effects of propofol.

4.3 Pharmacokinetics

Blood concentrations of propofol exhibit a tri-exponential decline in both dogs and cats. This is likely to reflect rapid distribution of propofol from the blood and brain to less well vascularised tissues, rapid metabolic clearance and slower redistribution from poorly vascularised tissues to blood. It is the first phase ($t_{1/2,\ alpha}$ approximately 10 min) that is clinically relevant, since animals awaken subsequent to the initial redistribution of propofol from the brain. The clearance of the drug is high in dogs (58.6 ml/kg.min) but lower in cats (8.6 ml/kg.min), possibly due to inter-species differences in metabolism. In dogs, clearance is higher than hepatic blood flow, suggesting the presence of metabolic sites in addition to the liver. The volume of distribution is high in both dogs (4.9 l/kg) and cats (8.4 l/kg).

The main method of elimination is through renal excretion of propofol metabolites.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

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

5.3 Special precautions for storage

Do not freeze.
The veterinary medicinal product should be used immediately after opening the vial. Product remaining in the container should be discarded.

5.4 Nature and composition of immediate packaging

Colourless type I glass vials, closed with a siliconised bromobutyl rubber stopper and an aluminium cap.

Pack sizes:

Box containing 5 x 20 ml vials
Box containing 1 x 50 ml vial

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF MARKETING AUTHORISATION HOLDER

Axience

7. MARKETING AUTHORISATION NUMBER(S)

VPA22873/001/001

8. DATE OF FIRST AUTHORISATION

01/03/2017

9 DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

26/06/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).