

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

PropoClear 10 mg/ml Emulsion for Injection for Cats and Dogs, Propofol.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances

Propofol	10.0 mg
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Excipients

Methyl parahydroxybenzoate E218	1.8 mg
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Propyl parahydroxybenzoate E216	0.2 mg
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For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Emulsion for injection.

Clear, colourless microemulsion, becoming cloudy on cooling.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats

4.2 Indications for use, specifying the target species

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

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

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

4.3 Contraindications

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients. Do not use when general anaesthesia or sedation are contraindicated.

4.4 Special warnings for each target species

Appropriate analgesia should be provided for animals undergoing painful procedures.

If the product is injected very slowly, an inadequate plane of anaesthesia can occur.

4.5 Special precautions for use

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 PropoClear, facilities for the maintenance of a patent airway and artificial ventilation should be available. In case of apnoea or hypotension, oxygen supplementation (or enrichment) must be readily 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.

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

Elderly and debilitated animals require lower doses and slower injection.

Do not use in animals less than 12 weeks of age.

Pharmacokinetic studies indicate that clearance of propofol is slower in greyhounds compared to other breeds of dogs. Sighthounds may, therefore, show a slightly longer duration of recovery from anaesthesia than other dog breeds.

Ensure that the product is clear before administration (see also Section 6.4).

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

This is a potent drug and particular care should be taken to avoid accidental self-administration. Preferably use a guarded needle until the moment of injection.

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.

People with known hypersensitivity to propofol should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Hypothermia, cardiovascular effects (decreased heart rate, decreased blood pressure) and respiratory depression (apnoea, decreased oxygen saturation) have been very commonly reported in dogs.

In cats, cardiovascular effects (decreased heart rate, decreased blood pressure and tachycardia) have been commonly reported, as well as respiratory depression (apnoea, hypoxia and bradypnea). Emesis was also commonly observed.

On rare occasions pain on injection has been observed, associated with perivascular administration.

Immediate or delayed swelling may develop at the injection site on rare occasions. The swelling may be extensive and extend to the entire limb. Mobility may be affected until the swelling resolves. While the swellings generally disappear without treatment, treatment may be necessary in some cases.

4.7 Use during pregnancy, lactation or lay

Pregnancy:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in dogs and cats. Studies in laboratory animals have shown that propofol crosses the placental barrier and therefore embryos are exposed to propofol in a dose-dependent way.

Used only accordingly to the benefit/risk in cases of induction prior to caesarean section in bitches.

Lactation:

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

4.8 Interaction with other medicinal products and other forms of interaction

The product has been used in association with commonly used premedicants acepromazine (a phenothiazine), butorphanol (an opiate), medetomidine (an α_2 adrenoceptor agonist), and midazolam (a benzodiazepam). No pharmacological interactions have been encountered. The potential for apnoea is increased when propofol is combined with opiates.

Propofol has no parasympatholytic properties. Pre-medication with an anticholinergic product should, therefore, be taken into consideration when propofol is combined with products which lower heart rate.

Pre-anaesthetics may increase the anaesthesia or sedative effect of propofol injection and lead to potentially dangerous arrhythmias. Medications for treatment of arrhythmias should be immediately available.

The product should not be mixed with other therapeutic agents or infusion fluids prior to administration.

4.9 Amounts to be administered and administration route

PropoClear is a sterile product for intravenous administration. Shake thoroughly before opening. Ensure that the product is clear and colourless before administration. Gentle warming and agitation will speed the process. Vial stoppers must not be broached more than 10 times.

Induction:

Dogs: The guidance induction dose for dogs is up to 6.5 mg/kg (0.65 ml/kg) body weight; the dose should be titrated against the response of the patient and may be administered over a period of 30-60 seconds. The use of pre-anaesthetics may significantly reduce propofol requirements.

Cats: The guidance induction dose for cats is up to 8.0 mg/kg (0.80 ml/kg) body weight; the dose should be titrated against the response of the patient and may be administered over a period of 30-60 seconds. The use of pre-anaesthetics may significantly reduce propofol requirements.

Maintenance:

Dogs: The guidance maintenance dose for dogs is 1.6 to 2.2 mg/kg (0.16 to 0.22 ml/kg) body weight; the dose should be titrated against the response of the patient and for individual dogs the dose required may be considerably less; the dose may be administered over a period of 10-30 seconds. The use of pre-anaesthetics may significantly reduce propofol requirements.

Cats: The guidance maintenance dose for cats is 1.1 to 3.3 mg/kg (0.11 to 0.33 ml/kg) body weight; the dose should be titrated against the response of the patient and may be administered over a period of 10-30 seconds. The use of pre-anaesthetics may significantly reduce propofol requirements.

Maintenance by inhalation agents: Where inhalation agents are used to maintain general anaesthesia, clinical experience indicates that there may be a need to use a higher initial concentration of inhalation agent than is normally the case following induction with barbiturate agents such as thiopentone.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Rapid administration or accidental overdose of propofol may cause cardiopulmonary depression. Respiratory arrest may be observed.

Respiratory depression should be treated by artificial ventilation with oxygen. Cardiovascular depression should be treated with the use of plasma expanders, pressor agents, antiarrhythmic agents, or other techniques as appropriate for the observed abnormality.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: anaesthetics

ATC vet code: QN01 AX 10

5.1 Pharmacodynamic properties

Propofol is a substituted phenol which, when given by intravenous injection, is a potent short-acting anaesthetic with a rapid rate of onset. Propofol produces unconsciousness by its depressant action on the central nervous system. Duration of anaesthesia afforded by a propofol induction dose ranges from 4 to 6 minutes in dogs and 2 to 6 minutes in cats depending on the pre-medicant used. Propofol has no analgesic properties.

5.2 Pharmacokinetic properties

After a single intravenous bolus administration, propofol is rapidly distributed and eliminated. The elimination half-lives are 7 hours and 23 minutes in cats and dogs, respectively.

No accumulation of propofol in blood has been observed after multiple daily dosing. Propofol is rapidly metabolised into propofol glucuronic acid conjugate and conjugates of hydroxy propofol. Urinary excretion is the major route of elimination of metabolites from the body.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Poloxamer 188
 Macrogol 400
 Propylene glycol
 Citric acid, monohydrate
 Methyl parahydroxybenzoate E218
 Propyl parahydroxybenzoate E216
 Sodium Hydroxide
 Water for Injection

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 30°C. Do not refrigerate. Exposure for an extended period to temperatures below 20°C may result in a cloudy appearance. A clear appearance will return upon allowing the product to warm to 20°C to 30°C. Gentle agitation will speed the process.

6.5 Nature and composition of immediate packaging

20 ml, 50 ml and 100 ml emulsion for injection contained in hydrolytic class type 1 colourless glass bottles with fluoro-resin coated chlorobutyl rubber stopper.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland
Trading as Pfizer Animal Health,
Ringaskiddy,
Co. Cork,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/158/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17th July 2009

10 DATE OF REVISION OF THE TEXT

9th September 2010

September 2010