IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10934/002/001**
Case No: 7006933

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Abbott Laboratories Limited

Abbott House, Vanwall Business Park, **Vanwall Road, Maidenhead**, **Berkshire SL6 4XE**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

PropoVet 10 mg/ml Emulsion for Injection

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation,unless revoked, shall continue in force from **18/01/2010**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

INN: Propofol

Each ml contains 10 mg of propofol

Excipient(s):

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Emulsion for injection.

An emulsion with a milk-like appearance, with no evidence of phase separation.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats

4.2 Indications for use, specifying the target species

PropoFlo is indicated for therapeutic use in dogs and cats as a short-acting, intravenous general anaesthetic with a short recovery period:

For procedures of short duration, lasting up to approximately 5 minutes.

For induction and maintenance of general anaesthesia by administration of incremental doses of the product to effect.

For induction of general anaesthesia where maintenance is provided by inhalation anaesthetic agents.

4.3 Contraindications

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

4.4 Special warnings for each target species

This product is a stable emulsion. Do not use if evidence of phase separation remains after gentle shaking.

If this 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 the product facilities for the maintenance of a patent airway, artificial ventilation and oxygen enrichment 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

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

The product is a potent drug, exercise caution to avoid accidental self-injection. Preferably use a guarded needle until the moment of injection. Ampoules should be opened with care to avoid cutting oneself. In case of accidental self-administration, seek medical advice immediately and show the package leaflet or label to the physician.

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

In case of splashes on the skin or in the eyes, wash off immediately.

4.6 Adverse reactions (frequency and seriousness)

Side-effects during induction, maintenance and recovery are uncommon. As with other anaesthetic agents, the possibility of respiratory or cardiovascular depression should be considered. During induction of anaesthesia, mild hypotension and transient apnoea may occur. See section 4.5. Induction is generally smooth, with minimal evidence of excitation (paddling of limbs, nystagmus, focal muscle twitching, opistotonus). During the recovery phase, vomiting and evidence of excitation has been observed in a small proportion of animals.

In clinical trials in cats, transient apnoea has been observed during induction. 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.

4.7 Use during pregnancy, lactation or lay

The safety of this product has not been established during pregnancy and lactation.

Pregnancy:
Use only accordingly to the benefit/risk assessment by the responsible veterinarian. Successful use of this product for induction prior to Caesarean section in bitches has been reported.

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

4.8 Interaction with other medicinal products and other forms of interaction

The product has been used after premedication with commonly used premedicants, e.g. atropine, acepromazine, diazepam, α-2 adrenoceptor agents, prior to maintenance with inhalational agents, e.g. halothane, nitrous oxide, enflurane, isoflurane and prior to administration of analgesic agents, e.g. pethidine, buprenorphine. No pharmacological incompatibility has been encountered.

The concurrent use of sedative or analgesic drugs is likely to reduce the dose of the product required to produce and maintain anaesthesia. See section 4.9.

4.9 Amounts to be administered and administration route

PropoFlo is a sterile product for intravenous administration.

General handling procedures

Prior to use, the product should be inspected visually for absence of particulate matter and discolouration and discarded if present. Shake the ampoule or vial gently but thoroughly before opening. See section 4.4 and 6.3.

Dosage for Induction by PropoFlo

The induction dose is calculated according to bodyweight and may be administered to effect over a period of 10-40 seconds. If the product is injected very slowly, an inadequate plane of anaesthesia can occur. The use of preanaesthetic drugs may markedly reduce propofol requirements. As with other sedative hypnotic agents, the amount of opioid, α-2 agonist and/or benzodiazepine premedication will influence the response of the patient to an induction dose of the product.

Where animals have been premedicated with an α-2 agonist such as medetomidine, the dose of propofol (as with any other intravenous anaesthetic agent) should be reduced by up to 85% (e.g. from 6.5 mg/kg for unpremedicated dogs to 1.0 mg/kg for dogs premedicated with an α-2 agonist).

The average induction dose for dogs and cats, either unpremedicated or when premedicated with a non-α-2 agonist tranquilliser such as acepromazine, is given in the table below. **These doses are for guidance only. The actual dose should be based on the response of the particular animal.**

	Dose mg/kg bodyweight	**Dose volume ml/kg bodyweight**
Dogs		
Unpremedicated	6.5 mg/kg	0.65 ml/kg
Premedicated		
- with non-α-2 agonist	4.0 mg/kg	0.40 ml/kg
- with an α-2 agonist	1.0 mg/kg	0.10 ml/kg
Cats		
Unpremedicated	8.0 mg/kg	0.80 ml/kg
Premedicated		
- with non-α-2 agonist	6.0 mg/kg	0.60 ml/kg
- with an α-2 agonist	1.2 mg/kg	0.12 ml/kg

Dosage for Maintenance by PropoFlo

When anaesthesia is maintained by incremental injections, the dose rate will vary between animals. Administer incremental doses of the product to effect by giving small doses of around 0.1ml/kg bodyweight (1.0mg/kg bodyweight) of the induction dose when anaesthesia becomes too light. These doses may be repeated as often as required, allowing 20-30 seconds to assess the effect before further increments are given. Experience has shown that doses of approximately 1.25-2.5 mg (0.125-0.25 ml) per kg bodyweight sustain anaesthesia for periods of up to 5 minutes.

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

Maintenance by inhalation agents

When inhalation agents are used to maintain general anaesthesia, experience indicates that it may be necessary to use a higher initial concentration of the inhalant anaesthetic than is usually required following induction with barbiturate agents such as thiopentone

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

Accidental overdosage is likely to cause cardio-respiratory depression. In cases of respiratory depression, stop drug administration, establish a patent airway, and initiate assisted or controlled ventilation with pure oxygen. Cardiovascular depression should be treated with plasma expanders, pressor agents, anti-arrhythmic agents or other techniques as appropriate for the observed abnormality.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: General anaesthetic
ATCvet code: QN01 AX 10

5.1 Pharmacodynamic properties

The product is a short-acting anaesthetic characterised by rapid onset and short duration of anaesthesia and by rapid recovery. The product produces unconsciousness by its depressant action on the central nervous system.

5.2 Pharmacokinetic properties

Intravenous injection is followed by extensive metabolism of propofol in the liver to inactive conjugates which are excreted in the urine (major route) and faeces. Elimination from the central compartment occurs rapidly, with an initial half-life of less than 10 minutes. After this initial phase, the decrease in plasma concentration is slower.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soya Oil
Lecithin, Egg
Glycerol (E422)
Nitrogen (E941)
Sodium Hydroxide (E524) for pH adjustment
Water for Injections

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 product as packaged for sale: 3 years

Discard any product remaining in the container following withdrawal of the required dose.

6.4 Special precautions for storage

Do not store above 25°C
Do not freeze

6.5 Nature and composition of immediate packaging

The product is supplied as a white aqueous isotonic emulsion for intravenous injection contained in:
- cartons of five vials (Type I glass) with bromobutyl rubber stoppers and flip off aluminium/polypropylene seals, containing 20ml of product (propofol 10mg/ml) (200mg propofol);
- cartons of five ampoules (Type I glass) containing 20ml of product (propofol 10mg/ml) (200mg propofol).

Not all pack sizes may be marketed.

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

Any unused product or waste materials should be disposed of in accordance with national requirements

7 MARKETING AUTHORISATION HOLDER

Abbott Laboratories Ltd
Abbott House
Vanwall Business Park
Vanwall Road
Maidenhead
Berkshire
SL6 4XE
UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10934/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28th November 2008

10 DATE OF REVISION OF THE TEXT

18th January 2010