Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetofol 10 mg/ml Emulsion for Injection for Cats and Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Propofol 10.0 mg
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Emulsion for injection.
A white homogeneous emulsion with no appearance of visible droplets or extraneous foreign particles.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

The veterinary medicinal product is a short-acting, intravenous, general anaesthetic for procedures of short duration, lasting up to 5 minutes:
For the induction and maintenance of general anaesthesia using incremental doses to effect,
For the induction of general anaesthesia where maintenance is provided by inhalation anaesthetics.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

The product is a stable emulsion; discard the vial if phase separation is observed. If the product is injected very slowly, an inadequate plane of anaesthesia can occur.

4.5 Special precautions for use

i. 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.

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

This is a potent drug: particular care should be taken to avoid accidental self-administration. A guarded needle should preferably be used 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 to the doctor. **Advice to Doctor:** Do not leave the patient unattended. Maintain airways and give symptomatic and supportive treatment.

iii. Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Side effects during induction, maintenance and recovery (including hypersensitivity reactions) are uncommon. Minimal evidence of excitation has been observed in a small proportion of animals. During the recovery phase, vomiting and evidence of excitation have been observed in a small proportion of animals.

In clinical trials in cats and dogs, transient apnoea during induction has been observed frequently. In cats paw/face licking characteristics during recovery have been observed in a small proportion of animals.

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.

Repeated anaesthesia with propofol in cats may cause oxidative injury and Heinz body production. Recovery may also become prolonged. Limiting repeated anaesthesia to intervals of more that 48 hours will reduce the likelihood.

4.7 Use during pregnancy, lactation or lay

The safety of this product in foetuses/neonates and during lactation has not been established, but the product has been used successfully for induction prior to Caesarean section in bitches.
Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

Propofol has been used in association with commonly used premedicants e.g. atropine, acepromazine, diazepam; inhalational agents e.g. halothane, nitrous oxide, enflurane and analgesic agents e.g. buprenorphine. No pharmacological incompatibility has been encountered.

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

4.9 Amounts to be administered and administration route

The product is indicated for intravenous administration to dogs and cats. Prior to use, the product should be inspected visually for absence of visible droplets or extraneous foreign particles and discarded if present. The vial should be shaken gently but thoroughly before opening.

Induction: The induction dose is calculated according to bodyweight and may be administered to effect over a period of 10 to 40 seconds. Alternatively, the calculated dose may be given in full as a single bolus over a shorter time interval. The induction dose is reduced by the use of premedicants.

The following dose rates are for guidance and in practice the dose rate should be based on response.
The average induction dose for dogs and cats, either unpremedicated or when premedicated with a non alpha-2-agonist tranquilliser such as acepromazine, is as follows:

	Dose rate (mg/kg bodyweight)	Dose volume (ml/kg bodyweight)
Dogs		
Unpremedicated	6.5	6.5 ml/10 kg
Premedicated	4.0	4.0 ml/10 kg
Cats		
Unpremedicated	8.0	2.0 ml/2.5 kg
Premedicated	6.0	1.5 ml/2.5 kg

Maintenance: Where anaesthesia is maintained by incremental injections, the dose rate will vary between animals. Incremental doses should be given to effect. Doses of around 1 ml per 4.0 – 8.0 kg bodyweight sustain anaesthesia for periods of up to 5 minutes.

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.

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

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

Accidental overdosage is likely to cause cardio-respiratory depression. Respiratory depression should be treated by artificial ventilation with oxygen. Cardiovascular depression requires the use of plasma expanders and pressor agents.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anaesthetics; Propofol

ATC Vet Code: QN 01 AX 10

5.1 Pharmacodynamic properties

Propofol (2,6 di-isopropylphenol, Diprivan; ICI 35868) is a nonbarbiturate substituted isopropyl phenol which is used for the induction and maintenance of anaesthesia. Propofol is a short-acting, intravenous general anaesthetic for procedures of short duration, lasting up to 5 minutes. Recovery from anaesthesia is usually rapid.

5.2 Pharmacokinetic particulars

After a single bolus dose, blood level profiles are characterised by a rapid distribution phase and a rapid elimination phase. No accumulation of blood levels has been observed after multiple daily dosing. Propofol is metabolised in the liver. Urinary excretion is the major route of elimination of metabolites from the body.

After intravenous administration to dogs at a dose rate of 6.5 mg propofol per kg bodyweight on one occasion, the following parameters were observed: C_{max} of 6.20 ± 0.602 microgram/ml, volume of distribution of 0.938 ± 0.0896 L/kg, T½ (alpha) 1.61 ± 0.239 minutes and T½ (beta) 29.5 ± 7.06 minutes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Egg Lecithin
Glycerol
Soybean Oil, refined
Sodium Hydroxide
Water for Injections

6.2 Major incompatibilities

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

6.3 Shelf-life

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

Withdrawn product should be used immediately. Product remaining in the container should be discarded.

6.4 Special precautions for storage

Do not store above 25°C.
Do not freeze.
Keep vial in the outer container in order to protect from light.
Store vials in the upright position.
Avoid introduction of contamination.

6.5 Nature and composition of immediate packaging

20ml and 50ml type I clear glass vials sealed with bromobutyl bungs and aluminium seals.

Available in cartons of 1 x 20ml, 1 x 50ml, 5 x 20ml and 5 x 50ml.

Not all pack sizes may be marketed.

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

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

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/109/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31 August 2012
Date of last renewal: 29 November 2013

10 DATE OF REVISION OF THE TEXT

January 2019