SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product

Norofol 10mg/ml Emulsion for Injection for cats and dogs

2. Qualitative and Quantitative Composition

Each ml contains:

Active Substance
Propofol 10.0mg

Excipients
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:*

Norofol Injection is indicated for use in dogs and cats as 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 that are hypersensitive to the active substance or any of the excipients.

4.4 *Special Warnings for Each Target Species:*

If Norofol Injection is injected very slowly, an inadequate plane of anaesthesia can occur.

Shake the vial gently but thoroughly before opening. Do not use if evidence of phase separation remains after gentle shaking.

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.

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

When using Norofol Injection, 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.

Sighthounds may have a slightly longer duration of recovery from anaethesia compared to other breeds of dog.

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

(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 case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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

4.6 *Adverse reactions (Frequency and Seriousness):*

Side effects during induction, maintenance and recovery are uncommon. Induction is generally smooth, 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. As with other anaesthetic agents, the possibility of respiratory and cardiovascular depression should be considered.

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

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 formation. Recovery may also be prolonged. Limiting repeated anaesthesia to intervals of more than 48 hours will reduce the likelihood.

4.7 *Use During Pregnancy, Lactation or Lay:*

Propofol has not been used in dogs and cats where the pregnancy is to be maintained, but has been used successfully for induction prior to Caesarean section in bitches.

The safety of Propofol in fetuses/neonates and during lactation has not been established.

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

4.8 *Interaction with other Medicinal Products and Other Forms of Interaction:*

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. pethidine, buprenorphine. No pharmacological interactions have been encountered.

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

4.9 *Amounts to be Administered and Administration Route :*

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

Induction: The induction dose is calculated according to bodyweight and may be administered to effect over a period of 10 to 40 seconds. The induction dose is reduced by the use of premedicants.

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 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-α-2 agonist tranquilliser such as acepromazine or an α-2 agonist, is as follows:

	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 α-2 agonist	1.0 mg/kg	0.10 ml/kg
Cats		
Unpremedicated	8.0 mg/kg	0.8 ml/kg
Premedicated		
With non-α-2 agonist	6.0 mg/kg	0.60 ml/kg
With α-2 agonist	1.2 mg/kg	0.12 ml/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 approximately 1.25 – 2.5mg (0.125 – 0.25ml) per 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 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 Properties

Pharmacotherapeutic group: Anesthetics.

ATC Vet Code: QN01AX10

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 anesthesia. 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 properties:*

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. Urinary excretion is the major route of elimination of metabolites from the body.

After intravenous administration of Norofol 10mg/ml Emulsion for Injection to dogs at a dose rate of 6.5 mg propofol per kg bodyweight on one occasion, the following parameters were observed: Volume of distribution of 0.938 $\pm$ 0.0896 L/kg, T½ (alpha) 1.61 $\pm$ 0.239 minutes and T½ (beta) 29.5 $\pm$ 7.06 minutes.

6. Pharmaceutical Particulars

6.1 *List of Excipient(s):*

Lecithin
Glycerol
Refined Soybean Oil
Sodium Hydroxide
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 veterinary medicinal product as packaged for sale: 2 years.

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

6.4 ***Special Precautions for Storage:***

Do not store above 25°C.
Do not freeze.
Protect from light.
Keep the container in the outer carton.
Store vials in the upright position.

6.5 ***Nature and Composition of Immediate Packaging:***

Norofol Injection is presented in 20 ml and 50 ml type I clear glass vials sealed with bromobutyl bungs and aluminium caps.
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 Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4275

9. DATE OF FIRST AUTHORISATION

09 January 2009

10. DATE OF REVISION OF THE TEXT

December 2013

Approved: **23/12/2013**