

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetofol 1.0% w/v Emulsion for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Propofol 1.0% w/v

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 extreneous foreign particles.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use, specifying the target species

Vetofol 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. The product is particularly suitable for cases where a short recovery period is desired.

4.3 Contraindications

None

4.4 Special Warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

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

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.

Inadvertent perivascular administration rarely causes local tissue reactions.

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 very slowly, an inadequate plane of anaesthesia can occur.

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. 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 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.

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.

If panting is evident before induction, it may continue throughout the subsequent periods of anaesthesia and recovery.

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.

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 incompatibility has been encountered.

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.

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. 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 tranquilliser such as acepromazine, is as follows:

	<i>Dose rate (mg/kg bodyweight)</i>	<i>Dose volume (ml/kg bodyweight)</i>
<u>Dogs</u>		
Unpremedicated	6.5	6.5 ml/10 kg
Premedicated	4.0	4.0 ml/10 kg
<u>Cats</u>		
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.

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

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anaesthetic

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soya Bean Oil, Refined
Lecithin, (Egg)
Glycerol
Nitrogen
Sodium Hydroxide
Water for Injections

6.2 Incompatibilities

Vetofol Injection should not be mixed with other medicinal products.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.

Do not freeze.

Protect from light.

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

Avoid the introduction of contamination.

6.5 Nature and composition of immediate packaging

20 ml and 50 ml type I clear glass vials sealed with bromobutyl bungs (Stelmi 6720) and aluminium or blue flip off caps.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 02000/4244

9. DATE OF RENEWAL OF THE AUTHORISATION

13 July 2010

10. DATE OF REVISION OF THE TEXT

March 2011