IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10277/030/001**
Case No: 7006071

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:

Schering Plough Limited

Shire Park, **Welwyn Garden City**, **Hertfordshire AL7 1TW**, **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:

Rapinovet 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 **06/11/2009**.

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

Rapinovet 10 mg/ml Emulsion for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Propofol 10mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Emulsion for injection.

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 general anaesthesia where maintenance is provided by inhalation anaesthetics.

4.3 Contraindications

None known.

4.4 Special warnings for each target species

Inadvertant perivascular administration rarely causes local tissue reactions.

4.5 Special precautions for use

Special precaution(s) 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 Rapinovet 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.

If Rapinovet 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 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, with minimal evidence of excitation. During the recovery phase, vomiting and evidence of excitation have been observed in a small proportion of animals.

In clinical trials in cats, transient apnoea during induction 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.

4.7 Use during pregnancy, lactation or lay

Rapinovet 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.

No information is available on the use of this product in lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Rapinovet 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.

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

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

It should be noted that the dose rates shown 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:

	Dose rate	**Dose volume**
	mg/kg	**ml/kg**
	bodyweight	**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 by Rapinovet: Where anaesthesia is maintained by incremental injections, the dose rate will vary between animals. Incremental doses should be given to effect. Experience in clinical trials has shown that doses of around 1 ml per 4.0-8.0 kg bodyweight sustain anaesthesia for periods of up to five 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.

Administration: By intravenous injection. The ampoule should be shaken thoroughly before opening. The emulsion should not be mixed with other therapeutic agents or infusion fluids prior to administration.

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: Anesthetics, propofol.
ATCvet code QN01AX10

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.

5.2 Pharmacokinetic properties

After a single bolus administration, blood level profiles are characterised by a rapid distribution phase and a rapid elimination phase. No accumulation of propofol in blood 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

Refined Soya Oil
Lecithin egg
Glycerol
Sodium Hydroxide
Water for Injection

6.2 Incompatibilities

None known

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and composition of immediate packaging

20 ml clear, colourless type I glass vial closed with rubber stopper.

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

Any portion of the contents remaining after use should be discarded. Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Schering-Plough Limited,
Schering-Plough House,
Shire Park,
Welwyn Garden City,
Hertfordshire,
AL7 1TW,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/030/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th July 2009

10 DATE OF REVISION OF THE TEXT

6th November 2009