According to a tolerance study:

**Effects of PropoFlo™ (propofol) Plus with Benzyl Alcohol Similar to Those of PropoFlo™**

Laliberté, Josee J.: A tolerance study following intravenous dose administration of PropoFlo Plus in Beagle dogs. Study Number 04-03-IT-D-TL-H. This tolerance study was conducted to evaluate the tolerance of young-adult non-premedicated Beagle dogs (n = 4) to doses of PropoFlo Plus (at 1x and 3x the standard dose) in comparison to PropoFlo (at 3x the standard dose). Every animal received each treatment with at least a 7 day wash out period between treatments.

The preservative in PropoFlo Plus has no significant effect on the safety or efficacy of PropoFlo.

<table>
<thead>
<tr>
<th>Treatment Description</th>
<th>Anaesthesia Duration</th>
<th>Maximum Heart Rate (beats per minute) Observed Immediately After Injection (Standard Deviation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PropoFlo (19.5 mg/kg) 3x standard dose</td>
<td>13.2 min.</td>
<td>193 (28.7)</td>
</tr>
<tr>
<td>PropoFlo Plus (6.5 mg/kg) 1x standard dose</td>
<td>6.7 min.</td>
<td>183 (22.2)</td>
</tr>
<tr>
<td>PropoFlo Plus (19.5 mg/kg) 3x standard dose</td>
<td>15.6 min.</td>
<td>218 (12.6)</td>
</tr>
<tr>
<td>PropoFlo (19.5 mg/kg) 3x standard dose</td>
<td>15.3 min.</td>
<td>195 (5.8)</td>
</tr>
</tbody>
</table>

- Given the same dose of PropoFlo and PropoFlo Plus (19.5 mg/kg; 3x normal dosing), duration and heart rate were comparable.
- The safety and efficacy of PropoFlo and PropoFlo Plus were similar in a head-to-head trial.
- The recommended dose of PropoFlo Plus should not be exceeded because it could lead to serious side effects.

Learn more. Contact your local Abbott Animal Health Territory Manager.

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Please use medicines responsibly. www.noah.co.uk/responsible/

PropoFlo Plus contains propofol. Legal Category POM-V UK.
PRESCRIBING INFORMATION

Active Ingredients: INN: Propofol E a c h ml contains 10 mg propofol and benzyl alcohol 20mg/ml

Indications for use: PropoFlo Plus 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 of general anaesthesia where maintenance is provided by inhalation anaesthetic agents. For induction and short-term maintenance of general anaesthesia by administration of incremental doses of PropoFlo Plus to effect for approximately half an hour (30 minutes), not to exceed the total dose stated in contraindications.

Contra-indications: Do not use for prolonged infusion. Do not exceed a total dose in one anaesthetic episode of 24 mg/kg (2.4 ml/kg) of propofol in cats or dogs. Do not use in animals younger than 5 months. Do not use in the pregnant animal or for Caesarean sections. Do not re-administer PropoFlo Plus to the same cat within 10 days. Do not use in animals with a known hypersensitivity to propofol or to any of the excipients found in this product.

Undesirable effects: 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. During the recovery phase, vomiting and excitation have 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. Heinz body formation may occur in cats with repeated exposure.

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 PropoFlo Plus, facilities for the maintenance of a patent airway, artificial ventilation and oxygen supplementation must be immediately 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. This product should not be used for induction and maintenance of general anaesthesia by incremental doses that would exceed total dose limits specified in Contraindications, due to the potential for toxic effects caused by the preservative, benzyl alcohol (see Overdose). Special precautions to be taken by the person administering the veterinary medicinal product to animals: Use aseptic techniques when administering the product. People with known hypersensitivity to any of the ingredients should avoid contact with the veterinary medicinal product. PropoFlo Plus is a potent drug, exercise caution to avoid accidental self-injection. Preferably use a guarded needle until the moment of injection. In the event of accidental self-administration, seek medical attention and show the label to the doctor. 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.

Use during pregnancy and lactation: The safety of this product in foetuses/neonates (including Caesarean sections) and during lactation has not been established. Parenteral products containing benzyl alcohol are not used in newborn infants in man (see contraindications). Pregnancy: Use only according to the benefit/risk assessment by the responsible veterinarian. Lactation: Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicaments and other forms of interaction: Propofol 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, sevoflurane, 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 PropoFlo Plus required to produce and maintain anaesthesia.

Special warnings for 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.

Withdrawal periods: Not applicable.

Overdose: 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.

Propofol — A single dose of 19.5 mg/kg (1.95 ml/kg) in dogs and bolus and intermittent doses totalling 24 mg/kg (2.4 ml/kg) in cats were well tolerated. Bolus and intermittent doses totalling 38.6 mg/kg (3.9 ml/kg) produced paraesthesia in one of four cats and prolonged recovery in all four cats treated.

Benzyl Alcohol (preservative) — Benzyl alcohol toxicity may lead to prolonged recovery and hyperkinesia in cats, and neurological signs such as tremors in dogs and fatalities in both species. There is no specific antidote; supportive treatment should be given.

In dogs, lethal doses of benzyl alcohol could result from administration of the maximum total dose of propofol stated in section 4.3, every hour for 9 hours, based on pharmacokinetic modelling and literature reports. In cats, lethal doses of benzyl alcohol could occur within 6.5 hours of administration, based on literature reports, direct estimation and maintenance dose rates.

See Summary of Product Characteristics for further information.

Further information available from:
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Legal Category: POM-V
Not to be sold to animal owners.

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