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ANAFOL 10 mg/mL INJECTION

ACTIVE CONSTITUENT: PROPOFOL 10 mg/mL

CLAIMS: For use as a general anaesthetic agent in dogs and cats.

PRESENTATION: 20 mL and 100 mL

RESTRAINTS: NOT TO BE USED IN FOOD PRODUCING SPECIES OF ANIMAL

PRECAUTIONS

During induction of anaesthesia, transient apnoea and mild hypotension may occur. Respiration should be monitored and facilities should be available for maintenance of the patient's airway, artificial ventilation and oxygen enrichment.

Use with caution in patients with cardiac, respiratory, renal or hepatic disorders, hypovolaemia or debilitation.

Safety of use in pregnancy has not been investigated, however propofol may be used for caesarean section in dogs.

SIDE EFFECTS

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

This product contains SOLUTOL HS15 which has been associated with anaphylactoid type skin hypersensitivity reactions in animals.

Reports of a low incidence (<0.5%) of anaphylactoid type skin hypersensitivity reactions following intravenous administration of propofol appear to be related to the inclusion

of the solubilizing agent SOLUTOL HS15 in the formulation. Such reactions primarily consist of transient swelling, urticaria and hyperaemia around the head, ventral abdomen or other body parts. Such reactions are not considered clinically significant and are expected to resolve rapidly and completely following administration of antihistamine and/or corticosteroids. There is some suggestion that slightly higher incidence of skin hypersensitivity reactions may occur in terrier breeds (Fox terriers, miniature Fox terriers and Jack Russell Terriers).

Safety studies conducted by the manufacturer of SOLUTOL HS15 in dogs indicate that anaphylactoid type skin hypersensitivity reactions associated with spontaneous release of histamine may occur sporadically in dogs when that material is administered at dosage of 50 mg/kg bodyweight, with increased likelihood or severity of reactions with increased dosage. In the safety studies all reactions resolved rapidly (within 10 to 30 minutes at SOLUTOL HS15 dosage of 100 mg/kg bodyweight} without treatment.

Dosing with Anafol 10 mg/ml Injection according to label recommended dose rates for unpremedicated animals results in administration of SOLUTOL HS15 65 mg/kg bodyweight to dogs and 80 mg/kg bodyweight to cats.

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To reduce the risk of occurrence of anaphylactoid type skin hypersensitivity reactions the following recommendations are provided:

1. Administer Anafol 10 mg/ml Injection SLOWLY by intravenous injection to effect. As with all anaesthetic agents dose recommendations are provided as an indication only.
2. Use premedication prior to administration of Anafol 10 mg/ml Injection, to reduce the total amount of anaesthetic agent required
3. Consider incorporation of an antihistamine agent in the premedication protocol
4. Consider incorporation of sedative agents in the anaesthetic induction regime, for example diazepam.
5. For prolonged procedures gaseous maintenance is recommended

Adverse effects associated with Propofol anaesthesia are uncommon and generally of a similar nature to those observed with other intravenous anaesthetic agents, including respiratory depression and minimal hypotension during induction and/or maintenance, and vomiting and spontaneous movements such as muscle twitching and opisthotonos during recovery. The most commonly reported adverse effect associated with administration of propofol is apnea during induction of anaesthesia, the incidence of which may be reduced by avoiding rapid injection of propofol. Respiration should be monitored following propofol administration to allow artificial oxygenation if required.

In cats, large doses of propofol for induction and maintenance of anaesthesia repeated daily for 5 - 7 days have reportedly caused a significant increase in Heinz bodies in the blood and clinical illness which resolved following cessation of propofol administration. Lower doses of propofol administered in cats on a daily basis for 4 weeks for induction only resulted in an increase in Heinz bodies but no adverse clinical or behavioural effects. Repeated doses of propofol in cats are therefore not recommended unless the doses are low and haematologyical parameters are monitored

DOSAGE AND ADMINISTRATION

Administer by intravenous injection only.

Anafol 10 mg/mL Injection is believed to be stable for at least 6 months following first use, providing aseptic technique is followed. Following withdrawal of the first dose, use the remainder of the vial within 6 months or discard the unused portion.

The dose rates provided below are for use as a guide only. Anafol 10 mg/mL Injection should be administered to effect. The required dose of Anafol 10 mg/mL Injection is reduced by the prior administration of preanaesthetic agents.

INDUCTION

Dogs:

Unpremedicated: 6.5 mg/kg bodyweight.

Premedicated: 4.0 mg/kg bodyweight.

Cats:

Unpremedicated: 8.0 mg/kg bodyweight. Premedicated: 6.0 mg/kg bodyweight.

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PHARMACOLOGY

Propofol (2,6-cli-isopropylphenol) is a nonbarbiturate sedative/hypnotic agent which produces a rapid and smooth induction and reliable maintenance of general anaesthesia.

Propofol is highly lipid soluble and therefore rapidly crosses the blood-brain barrier, resulting in a rapid onset of action following intravenous administration. Propofol has a high affinity for body tissues due to its lipophilic nature and therefore exhibits a large volume of distribution. Propofol is highly bound to plasma proteins (95-99%).

Extensive redistribution and metabolism of propofol result in a short duration of action and a smooth and rapid recovery. Rapid hepatic biotransformation occurs via glucuronide conjugation to inactive metabolites which are primarily excreted by the kidneys. The elimination half-life in the dog is approximately 1.4 hours, with a clearance of approximately 50 ml/kg/minute. Due to its lipophilic nature, propofol crosses the placenta and passes into milk.

CLINICAL APPLICATION

Propofol was first introduced into veterinary anaesthesia over 20 years ago, and has since proven to be a safe and effective anaesthetic agent with a wide range of clinical applications and a number of advantages over other anaesthetic drugs.

The induction of anaesthesia which follows intravenous administration of propofol is rapid and smooth. Rapid induction allows a short time to intubation, where indicated, and early control of the animal's airway. Propofol anaesthetic induction is without the unpleasant and potentially damaging excitatory side effects sometimes observed with other anaesthetic agents. Unlike barbiturates, no evidence of tissue irritation or reaction has been observed following accidental perivascular administration of propofol.

The demonstrated compatibility between propofol and a wide variety of commonly used preanaesthetic agents and analgesics broadens the scope of propofol use in veterinary clinical practice through its inclusion in balanced anaesthetic protocols. The dose of propofol required to induce anaesthesia is significantly reduced by the administration of preanaesthetic agents prior to induction.

Anaesthesia induced by a single dose of propofol is of short duration, allowing a rapid emergence following short procedures. For longer procedures, propofol induction provides the versatility of a choice of maintenance with propofol or inhalation. Propofol is compatible with inhalational anaesthetic agents such as halothane and isoflurane. Alternatively, anaesthesia may be maintained through the administration of intravenous bolus injections of propofol as required.

A further advantage of propofol over anaesthetic agents such as barbiturates is the lack of a cumulative effect following "top-up" doses, such that maintenance of anaesthesia by repeated doses of propofol only minimally prolongs anaesthetic recovery time. Propofol anaesthesia may also be repeated on separate occasions in dogs without the development of tolerance or sensitivity, a useful characteristic where short procedures are performed on a regular basis e.g. daily bandage changes or radiotherapy.

Propofol provides a safer alternative to barbiturates in sighthounds, as the extended recovery periods commonly experienced with barbiturate anaesthesia in those breeds are not observed following propofol anaesthesia.

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The characteristically rapid recovery from propofol anaesthesia provides a relatively comfortable post-anaesthetic experience and allows the early discharge of the animal from the veterinary clinic.

Propofol has been successfully used for Caesarean sections in dogs and has been found to have a positive impact on neonatal survival. Rapid recovery from anaesthesia allows the bitch to begin caring for the puppies earlier, and the rapid clearance of the drug from the body may result in more vigorous puppies.

Anafol 10 mg/ml Injection is an aqueous solution containing an antimicrobial preservative and therefore does not support microbial growth. Anafol 10 mg/ ml Injection is presented in a multi-dose vial and sterility of the solution has been demonstrated for 6 months following withdrawal of the first dose.