EUTHASOL- pentobarbital sodium and phenytoin sodium solution
Virbac AH, Inc.

EUTHASOL®
(pentobarbital sodium and phenytoin sodium)
Euthanasia Solution

Approved by FDA under ANADA # 200-071

FOR DOGS ONLY

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

A non-sterile solution containing pentobarbital sodium and phenytoin sodium as the active ingredients. Rhodamine B, a bluish-red fluorescent dye, is included in the formulation to help distinguish it from parenteral drugs intended for therapeutic use. Although the solution is not sterile, benzyl alcohol, a bacteriostat, is included to retard the growth of microorganisms.

Each mL contains: *Active ingredients:* 390 mg pentobarbital sodium (barbituric acid derivative), 50 mg phenytoin sodium; *Inactive ingredients:* 10% ethyl alcohol, 18% propylene glycol, 0.003688 mg rhodamine B, 2% benzyl alcohol (preservative), water for injection q.s. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH.

ACTIONS

EUTHASOL® Euthanasia Solution (pentobarbital sodium and phenytoin sodium) contains two active ingredients which are chemically compatible but pharmacologically different. Each ingredient acts in such a manner so as to cause humane, painless, and rapid euthanasia. Euthanasia is due to cerebral death in conjunction with respiratory arrest and circulatory collapse. Cerebral death occurs prior to cessation of cardiac activity.

When administered intravenously, pentobarbital sodium produces rapid anesthetic action. There is a smooth and rapid onset of unconsciousness. At the lethal dose, there is depression of vital medullary respiratory and vasomotor centers.

When administered intravenously, phenytoin sodium produces toxic signs of cardiovascular collapse and/or central nervous system depression. Hypotension occurs when the drug is administered rapidly.

Pharmacodynamic Activity

The sequence of events leading to humane, painless, and rapid euthanasia following intravenous injection of EUTHASOL Euthanasia Solution is similar to that following intravenous injection of pentobarbital sodium, or other barbituric acid derivatives. Within seconds, unconsciousness is induced with simultaneous collapse of the dog. This stage

rapidly progresses to deep anesthesia with concomitant reduction in the blood pressure. A few seconds later, breathing stops, due to depression of the medullary respiratory center; encephalographic activity becomes isoelectric, indicating cerebral death; and then cardiac activity ceases.

Phenytoin sodium exerts its effect during the deep anesthesia stage caused by the pentobarbital sodium. This ingredient, due to its cardiotoxic properties, hastens the stoppage of electrical activity in the heart.

INDICATIONS

For use in dogs for humane, painless, and rapid euthanasia.

WARNING

For canine euthanasia only. Must not be used for therapeutic purposes. Do not use in animals intended for food.

ENVIRONMENTAL HAZARD: This product is toxic to wildlife. Birds and mammals feeding on treated animals may be killed. Euthanized animals must be properly disposed of by deep burial, incineration, or other method in compliance with state and local laws, to prevent consumption of carcass material by scavenging wildlife.

HUMAN WARNING

Caution should be exercised to avoid contact of the drug with open wounds or accidental self-inflicted injections. Keep out of reach of children. If eye contact, flush with water and seek medical advice/attention.

PRECAUTIONS

Euthanasia may sometimes be delayed in dogs with severe cardiac or circulatory deficiencies. This may be explained by the impaired movement of the drug to its site of action. An occasional dog may elicit reflex responses manifested by motor movement; however, an unconscious animal does not experience pain, because the cerebral cortex is not functioning.

When restraint may cause the dog pain, injury, or anxiety, or danger to the person making the injection, prior use of tranquilizing or immobilizing drugs may be necessary.

Dosage and Administration:

Dosage: Dogs, 1 mL for each 10 pounds of body weight.

Administration: Intravenous injection is preferred. Intracardiac injection may be made when intravenous injection is impractical, as in a very small dog, or in a comatose dog with impaired vascular functions. Good injection skill is necessary for intracardiac

injection.
The calculated dose should be given in a single bolus injection.

For intravenous injection, a needle of sufficient gauge to ensure intravenous placement of the entire dose should be used.

The use of a Luer-Lok® syringe is recommended to prevent accidental exposure due to needle/syringe separation.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Virbac AH, Inc. at 1-800-338-3659 or us.virbac.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

HOW SUPPLIED

EUTHASOL Euthanasia Solution is available in 100 mL multiple dose vials.

STORAGE

Store at controlled room temperature of between 20˚ and 25˚C (68˚and 77˚F), with excursions permitted between 15° to 30°C (59° to 86°F).

Manufactured by a nonsterilizing process.

Manufactured for **Virbac AH, Inc.**, PO Box 162059, Fort Worth, TX 76161

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EUTHASOL

pentobarbital sodium and phenytoin sodium solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:51311-050
Route of Administration	INTRAVENOUS	**DEA Schedule**	CIII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
pentobarbital sodium (UNII: NJJ0475N0S) (pentobarbital - UNII:I4744080IR)	pentobarbital sodium	390 mg in 1 mL
phenytoin sodium (UNII: 4182431BJH) (phenytoin - UNII:6158TKW0C5)	phenytoin sodium	50 mg in 1 mL

Product Characteristics			
Color	RED (bluish-red)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51311-050-01	100 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200071	05/05/2004	

Labeler - Virbac AH, Inc. (131568396)

Registrant - Virbac AH, Inc. (131568396)

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