

PENTOBARBITAL SODIUM AND PHENYTOIN SODIUM- pentobarbital sodium and phenytoin sodium injection, solution
Akorn Animal Health, Inc.

Pentobarbital Sodium and Phenytoin Sodium
Euthanasia Solution
CIII

FOR DOGS ONLY

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

DESCRIPTION:

A nonsterile 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), purified water qs. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH.

ACTIONS:

Pentobarbital Sodium and Phenytoin Sodium euthanasia solution 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 Pentobarbital Sodium and Phenytoin Sodium 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 eyes with water and seek medical 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.

ADVERSE REACTION:

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Akorn, Inc. at 1-800-932-5676. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

HOW SUPPLIED:

Pentobarbital Sodium and Phenytoin Sodium is available in 100 mL multi-dose vials in package of one, NDC 59399-185-90.

Manufactured by a nonsterilizing process.

Store at controlled room temperature 20° to 25°C (68° to 77°F).

Use contents within 60 days of first puncture. Approved by FDA under ANADA # 200-614

AKORN
ANIMAL HEALTH

Manufactured by: **Akorn, Inc.**
Lake Forest, IL 60045

VPP00N Rev. 12/19

Luer-Lok is a registered trademark of Becton, Dickinson and Company.

Principal Display Panel Text for Container Label:

NDC 59399-185-90

Pentobarbital Sodium
and Phenytoin

Sodium CIII




Euthanasia Solution

FOR DOGS ONLY

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

Approved by FDA under ANADA # 200-614

100 mL Akorn Animal Health Logo

<p>NDC 59399-185-90</p> <p>Pentobarbital Sodium and Phenytoin Sodium </p> <p>Euthanasia Solution FOR DOGS ONLY</p> <p>Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>Approved by FDA under ANADA # 200-614</p> <p>100 mL </p>	<p>No Varnish</p>	<p>Manufactured by a nonsterilizing process. Multi-Dose Vial Each mL contains: <i>active ingredients:</i> 390 mg pentobarbital sodium (barbituric acid derivative), 50 mg phenytoin sodium; <i>inactive ingredients:</i> 10% ethyl alcohol, 18% propylene glycol, 0.003688 mg rhodamine B, 2% benzyl alcohol (preservative), purified water qs. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH.</p> <p>For Intravenous or Intracardiac Use.</p> <p>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.</p> <p>Warning: For canine euthanasia only. Must not be used for therapeutic purpose. Do not use in animals intended for food.</p> <p>Human Warning: Refer to package insert for important human risk information.</p> <p>Store at controlled room temperature 20° to 25°C (68° to 77°F). Use contents within 60 days of first puncture.</p> <p>Read Product Information sheet carefully. See warnings above.</p> <p>Manufactured by: Akorn, Inc., Lake Forest, IL 60045</p>	 <p>59399-185-90</p>
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Principal Display Panel Text for Carton Label:

NDC 59399-185-90

Pentobarbital

Sodium and

Phenytoin

Sodium CIII

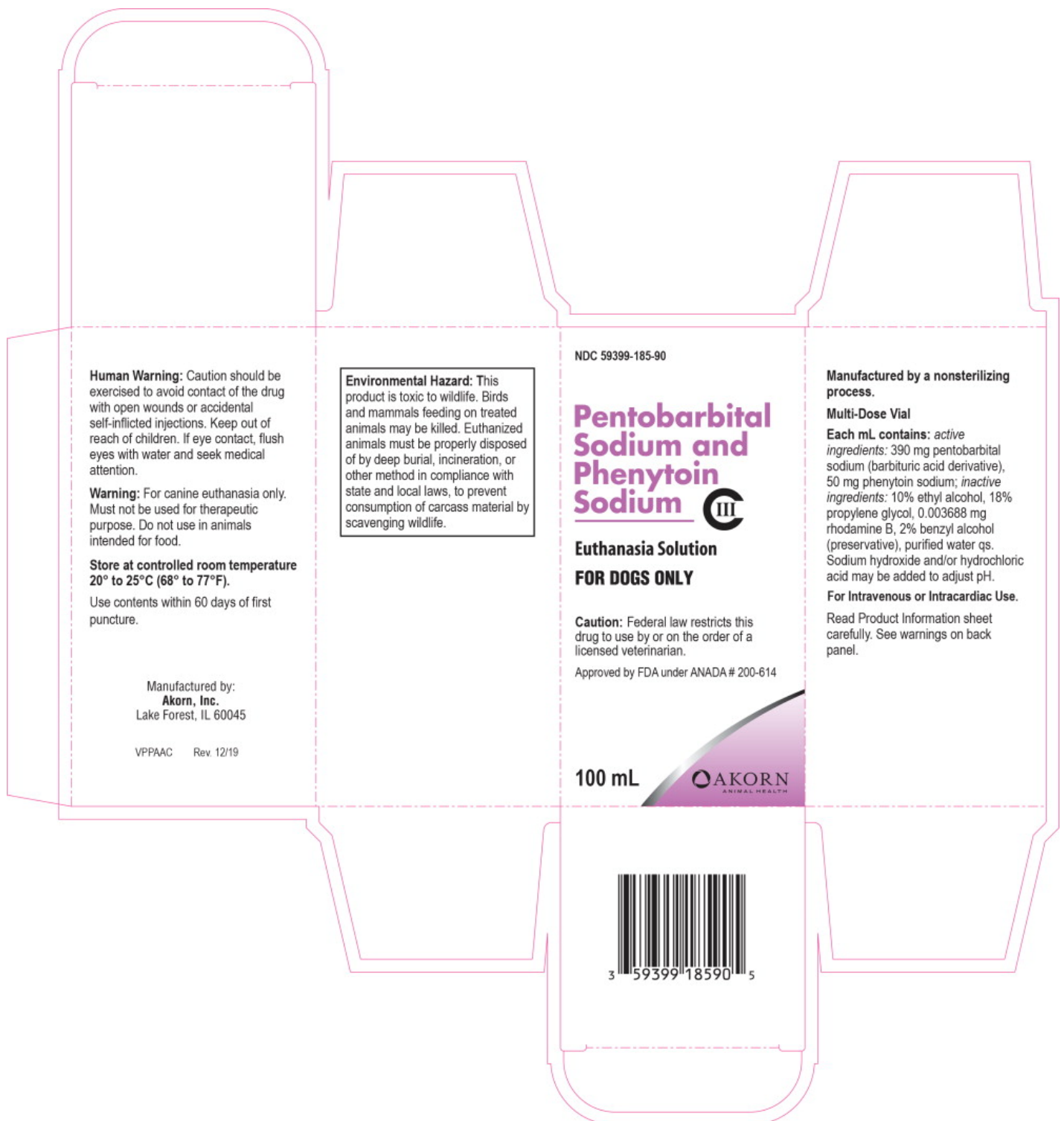
Euthanasia Solution

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Approved by FDA under ANADA # 200-614

100 mL Akorn Animal Health Logo



PENTOBARBITAL SODIUM AND PHENYTOIN SODIUM

pentobarbital sodium and phenytoin sodium injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:59399-185
Route of Administration	INTRACARDIAC, 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

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Rhodamine B (UNII: K7G5SCF8IL)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Hydrochloric Acid (UNII: QTT17582CB)	
Water (UNII: 059QF0KO0R)	
Benzyl Alcohol (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59399-185-90	1 in 1 CARTON		
1		100 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200614	02/07/2020	

Labeler - Akorn Animal Health, Inc. (117696748)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Pharmacal Co. Inc.		117696873	LABEL, MANUFACTURE, PACK