PENTOBARSOL- euthanasia injection, solution Dechra Veterinary Products, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Pentobarsol Injection

DESCRIPTION:

Pentobarsol (euthanasia) Injection

NDC 17033-085-25

FOR VETERINARY EUTHANASIA ONLY. Keep Out of Reach of Children.

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

6 grains of pentobarbital sodium

Net contents: 250 mL

DOSAGE AND ADMINISTRATION:

Mulitple Dose Vial

Dosage: For intravenous (preferred), intracardial, intrapleural, or intraperitoneal injection.

Small Animals: Inject rapidly 1 mL per 10 lbs. of bady weight. Minimum dose 1 mL.

Horses and other Large Animals: Inject rapidly 1 mL per 10 lbs. of obdy weight, to a maximum of 100 mL.

Each mL contains:

Pentobarbital sodium 6 gr.

Isopropyl alcohol 10%

Propylene glycol 18%

Benzyl alcohol 2.0%

Purified water qs

Green dye to establish a distinctive color.

TAKE TIME - OBSERVE LABEL DIRECTIONS

WARNING:

This is a highly toxic parenteral solution specifically designed for rapid, painless, and

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.

To report suspected adverse drug events, for technical assistance, or to obtain a copy of the Safety Data Sheet (SDS), contact Dechra at (866) 933-2472. For additional information about adverse drug experience reporting for animals, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae.

PENTOBARSOL is a trademark of Dechra Vetrinary Products, LLC.

Manufactured for:

Dechra Veterinary Products 7015 College Boulevard, Suite 525 Overland Park. KS 66211

Rev.: 01/2023

Multiple-dose vial

Dosage: For intravenous (preferred), intracardial, intrapleural, or intraperitoneal injection.

Small animals: 1 mL per 10 lb of body weight.

Horses and other large animals:

1 mL per 10 lb of body weight to a maximum dose of 100 mL.

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POISON



NDC 17033-085-25

PENTOBARSOL™ INJECTION ©

6 grains of pentobarbital sodium

EUTHANASIA INJECTION

FOR VETERINARY EUTHANASIA ONLY

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

Net contents: 250 mL



Keep out of reach of children.

Warning: This is a highly-toxic parenteral solution specifically designed for rapid, painless and humane euthanasia of animals.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Dechra at (866) 933-2472.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at

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Manufactured for:

Dechra Veterinary Products 7015 College Boulevard, Suite 525 Overland Park, KS 66211 USA

Rev. November 2022



Lot # / Exp. Date

PENTOBARSOL

euthanasia injection, solution

Product Information					
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:17033- 085		
Route of Administration	INTRAVENOUS, INTRACARDIAC, INTRAPLEURAL, INTRAPERITONEAL	DEA Schedule	CII		

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
PENTOBARBITAL SODIUM (UNII: NJJ0475N0S) (PENTOBARBITAL - UNII:14744080IR)	PENTOBARBITAL SODIUM	390 mg in 1 mL			

Inactive Ingredients				
Ingredient Name	Strength			
ISOPROPYL ALCOHOL (UNII: ND2M416302)	0.10 mL in 1 mL			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.180 mL in 1 mL			
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.02 mL in 1 mL			
WATER (UNII: 059QF0KO0R)	0.01 mL in 1 mL			

Product Characteristics					
Color	green (Green dye to establish a distinctive color.)	Score			
Shape		Size			
Flavor		Imprint Code			
Contains					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:17033-085-25	250 mL in 1 VIAL, MULTI-DOSE				

Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
	01/11/2023				
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date			

Labeler - Dechra Veterinary Products, LLC (362142734)

Registrant - Med-Pharmex, Inc. (025353699)

Establishment			
Name	Address	ID/FEI	Business Operations

Med-Pharmex, Inc. 025353699 manufacture

Establishment					
Name	Address	ID/FEI	Business Operations		
Siegfried USA, LLC		001213784	api manufacture		

Revised: 1/2023 Dechra Veterinary Products, LLC