

CESTEX- epsiprantel tablet, film coated
Zoetis Inc.

Cestex[®]
(epsiprantel)

Veterinary Tablets

Cestex (epsiprantel) tablets are indicated for the removal of tapeworms in the cat (*Dipylidium caninum* and *Taenia taeniaeformis*) and dog (*Dipylidium caninum* and *Taenia pisiformis*).

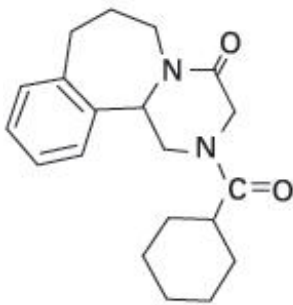
CAUTION

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

DESCRIPTION

Cestex tablets are film-coated and contain 12.5 mg, 25 mg, 50 mg or 100 mg of epsiprantel per tablet.

Epsiprantel is an anthelmintic that is active as a single dose against the common tapeworms of cats and dogs. Epsiprantel has a molecular weight of 326 and is chemically 2-(cyclohexyl-carbonyl)-4-oxo 1,2,3,4,6,7,8,12b-octahydropyrazino[2,1-a][2]benza-zepine. It is a stable white solid which is sparingly soluble in water. Its chemical structure is presented below.



Action

Epsiprantel acts directly on the tapeworm. Since it is minimally absorbed following oral administration, epsiprantel remains at the site of action within the gastrointestinal tract. Due to digestive process, tapeworm fragments or proglottids may not be readily visible in the stool.

INDICATIONS AND USAGE

Cestex tablets are indicated for the removal of the following:

Feline cestodes: *Dipylidium caninum* and *Taenia taeniaeformis*

Canine cestodes: *Dipylidium caninum* and *Taenia pisiformis*

CONTRAINDICATIONS

There are no known contraindications to the use of this drug.

WARNINGS

For use in cats and dogs only. Safety of use in pregnant or breeding animals has not been determined. Keep out of reach of children. Not for use in humans.

PRECAUTION

Do not use in kittens or puppies less than 7 weeks of age.

DOSAGE AND ADMINISTRATION

Cestex tablets should be administered orally.

The recommended dosage of epsiprantel is: cats, 1.25 mg/lb of body weight; dogs, 2.5 mg/lb of body weight. The following table may be used as a guide:

Dosage Schedule		
Feline		
Body Weight		Dose
Seven weeks old up to 10 lb		12.5 mg
11–20 lb		25.0 mg
Canine		
Body Weight		Dose
Seven weeks old up to 5 lb		12.5 mg
6–10 lb		25.0 mg
11–20 lb		50.0 mg
21–40 lb		100.0 mg
41–50 lb		125.0 mg
51–60 lb		150.0 mg
61–80 lb		200.0 mg
81–90 lb		225.0 mg
91–100 lb		250.0 mg
101+ lb	2.5 mg/lb, rounding up to next whole tablet combination	

Fasting is not necessary or recommended.

Unless exposure to the infected intermediate hosts is controlled, reinfection is likely and retreatment may be required. In the case of *D. caninum*, an effective flea control program should be instituted.

SAFETY

Epsiprantel has been evaluated in cats at 5 times the recommended dose given once daily for 3 days with no adverse effects noted. In tolerance studies, epsiprantel produced minimal clinical signs in cats given 40 times the recommended dose once daily for 4 days.

Epsiprantel has been evaluated in 14-day repeat dose studies in dogs at 500 mg/kg (90 times recommended dosage) with no significant adverse results. No side effects were observed during the clinical field studies.

Epsiprantel is not a cholinesterase inhibitor. During the course of clinical field studies, Cestex was administered concurrently with diethylcarbamazine citrate (dogs only), anti-inflammatory agents, insecticides, and nematocides with no drug incompatibilities noted.

STORAGE

Store at controlled room temperature 20°-25°C (68°-77°F) with excursions between 15°-30°C (59°-86°F).

HOW SUPPLIED

Cestex tablets are film-coated and contain 12.5 mg, 25 mg, 50 mg or 100 mg of epsiprantel per tablet. Cestex is supplied as described below:

Concentration	Weight (lbs)		Number Tablets/Bottle
	Cat	Dog	
12.5 mg	10	5	50, 100
25.0 mg	20	10	50, 100
50.0 mg	--	20	25, 50
100.0 mg	--	40	25, 50

Approved by FDA under NADA # 140-893

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Distributed by:

Zoetis Inc.

Kalamazoo, MI 49007

40027642

Revised: May 2019

PRINCIPAL DISPLAY PANEL - 12.5 mg Bottle Label

Cestex[®]

(epsiprantel)

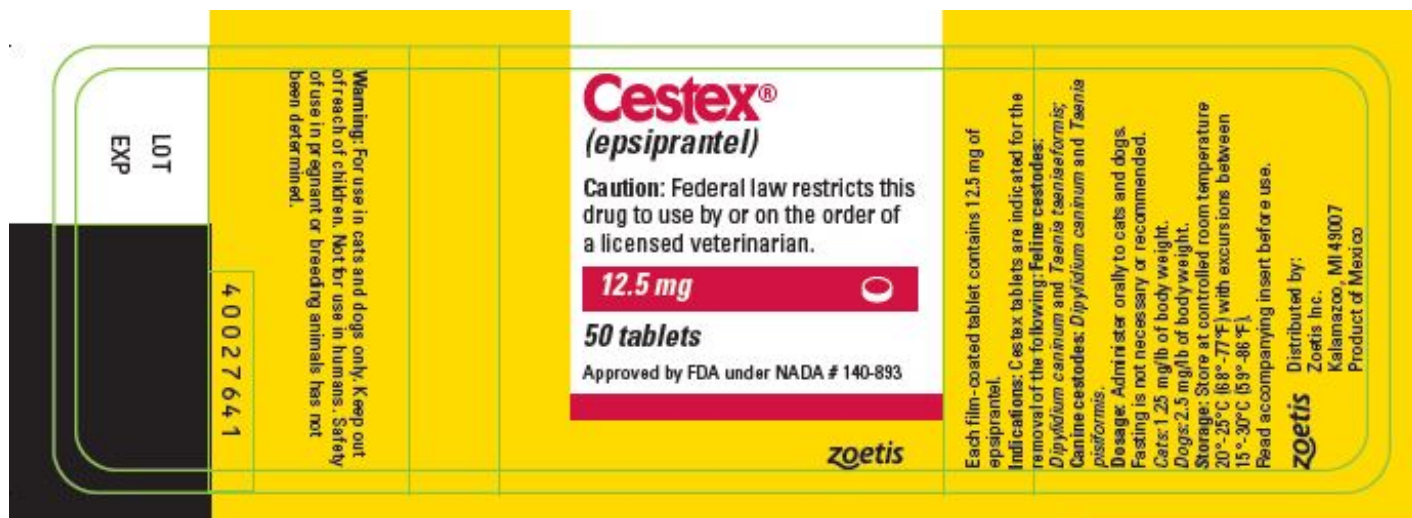
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12.5 mg

50 tablets

Approved by FDA under NADA # 140-893

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PRINCIPAL DISPLAY PANEL - 25 mg Bottle Label



PRINCIPAL DISPLAY PANEL - 50 mg Bottle Label



PRINCIPAL DISPLAY PANEL - 100 mg Bottle Label



CESTEX

epsiprantel tablet, film coated

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-8032
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
epsiprantel (UNII: 0C1SPQ0FSR) (epsiprantel - UNII:0C1SPQ0FSR)	epsiprantel	12.5 mg

Product Characteristics

Color	RED	Score	2 pieces
Shape	ROUND (bi-convex)	Size	6mm
Flavor		Imprint Code	219
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-8032-1	50 in 1 BOTTLE		
2	NDC:54771-8032-2	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140893	12/01/1989	

CESTEX

epsiprantel tablet, film coated				
Product Information				
Product Type		PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-8033
Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
epsiprantel (UNII: 0C1SPQ0FSR) (epsiprantel - UNII:0C1SPQ0FSR)			epsiprantel	25 mg
Product Characteristics				
Color	BROWN		Score	2 pieces
Shape	ROUND (bi-convex)		Size	8mm
Flavor			Imprint Code	220
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-8033-1	50 in 1 BOTTLE		
2	NDC:54771-8033-2	100 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NADA	NADA140893		12/01/1989	

CESTEX

epsiprantel tablet, film coated

Product Information

Product Type

PRESCRIPTION ANIMAL DRUG

Item Code (Source)

NDC:54771-8034

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

epsiprantel (UNII: 0C1SPQ0FSR) (epsiprantel - UNII:0C1SPQ0FSR)

epsiprantel

50 mg

Product Characteristics

Color

GRAY

Score

2 pieces

Shape	ROUND (bi-convex)	Size	10 mm
Flavor		Imprint Code	221
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-8034-1	25 in 1 BOTTLE		
2	NDC:54771-8034-2	50 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140893	12/0 1/1989	

CESTEX

epsiprantel tablet, film coated

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-8035
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
epsiprantel (UNII: 0C1SPQ0FSR) (epsiprantel - UNII:0C1SPQ0FSR)	epsiprantel	100 mg

Product Characteristics

Color	ORANGE (peach)	Score	2 pieces
Shape	ROUND (bi-convex)	Size	13mm
Flavor		Imprint Code	222
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-8035-1	25 in 1 BOTTLE		
2	NDC:54771-8035-2	50 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140893	12/0 1/1989	

Labeler - Zoetis Inc. (828851555)

Revised: 10/2019

Zoetis Inc.