

**CESTEX- epsiprantel tablet, film coated**  
**Zoetis Inc.**

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**Cestex<sup>®</sup>**  
**(epsiprantel)**

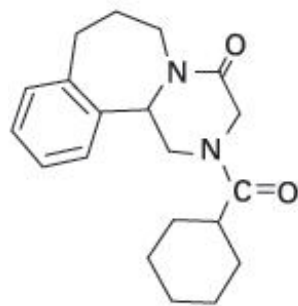
**Veterinary Tablets**

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**

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<b>Feline</b>	
<b>Body Weight</b>	<b>Dose</b>

Seven weeks old up to 10 lb	12.5 mg
11–20 lb	25.0 mg

**Canine**

<b>Body Weight</b>	<b>Dose</b>
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

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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:

<b>Concentration</b>	<b>Weight (lbs)</b>		<b>Number Tablets/Bottle</b>
	<b>Cat</b>	<b>Dog</b>	
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

NADA #140-893, Approved by FDA

Distributed by:  
Zoetis Inc.

Kalamazoo, MI 49007

13915900

Revised: January 2013

## PRINCIPAL DISPLAY PANEL - 12.5 mg Tablet Bottle Label

**Cestex<sup>®</sup>**  
**(epsiprantel)**

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

**12.5 mg**

**50 tablets**

NADA #140-893, Approved by FDA

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## PRINCIPAL DISPLAY PANEL - 25 mg Tablet Bottle Label

**Cestex<sup>®</sup>**  
**(epsiprantel)**

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

**25 mg**

**50 tablets**

NADA #140-893, Approved by FDA

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### PRINCIPAL DISPLAY PANEL - 50 mg Tablet Bottle Label

**Cestex**<sup>®</sup>  
(*epsiprantel*)

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

**50 mg**

**25 tablets**

NADA #140-893, Approved by FDA

**zoetis**



### PRINCIPAL DISPLAY PANEL - 100 mg Tablet Bottle Label

**Cestex**<sup>®</sup>  
(*epsiprantel*)

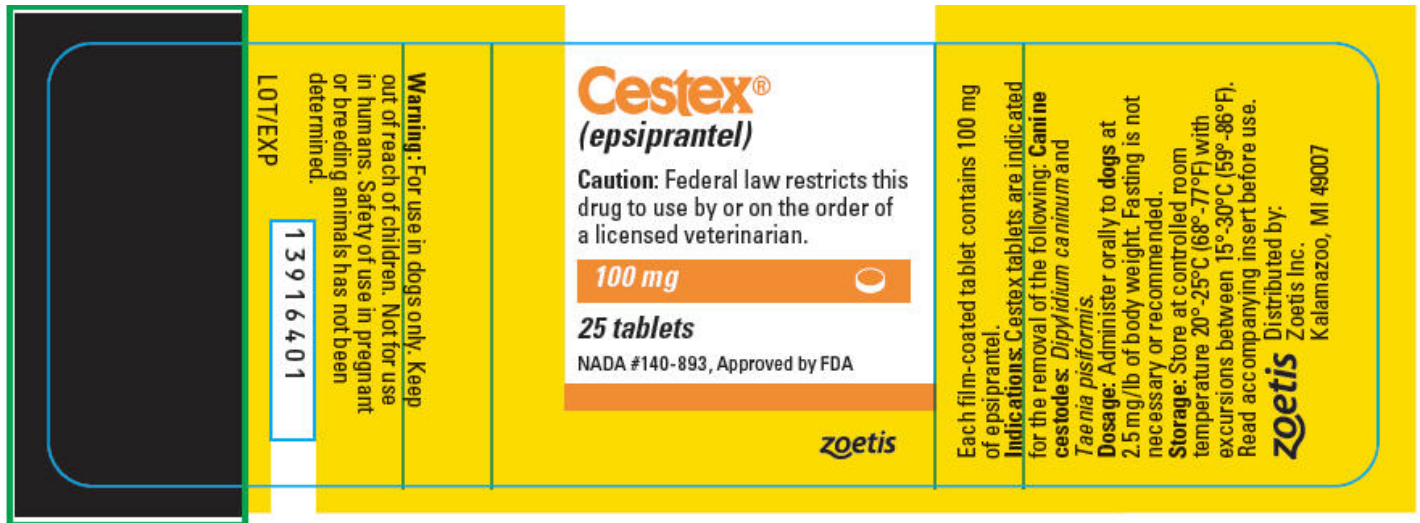
**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

100 mg

25 tablets

NADA #140-893, Approved by FDA

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## 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	10mm
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	12/01/1989	

## 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	12/01/1989	

**Labeler** - Zoetis Inc. (828851555)

## Establishment

Name	Address	ID/FEI	Business Operations
Zoetis LLC		039055157	MANUFACTURE

## Establishment

Name	Address	ID/FEI	Business Operations
Emcure Pharmaceuticals Ltd		862602830	MANUFACTURE, API MANUFACTURE

Revised: 3/2014

Zoetis Inc.