CESTEX- epsiprantel tablet, film coated Pfizer Animal Health

Cestex® (epsiprantel) Veterinary Tablets

CAUTION

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

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*).

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.

$$\begin{array}{c}
 & 0 \\
 & N \\
 & N \\
 & C = 0
\end{array}$$

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

Cestex tablets are indicated for the removal of the following:

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

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		
Ca	nine		
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.

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.

STORAGE

Store at controlled room temperature 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:

	Weight (lbs)		Number Tablets /Pottle
Concentration	Cat	Dog	Number Tablets/Bottle
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:

Animal Health

Exton, PA 19341, USA Div. of Pfizer Inc NY, NY 10017

75-8032-10 January 2004

PRINCIPAL DISPLAY PANEL - 50 12.5 mg Tablet Bottle Label

Ces tex[®] (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

Pfizer



PRINCIPAL DISPLAY PANEL - 100 12.5 Tablet Bottle Label

Ces tex[®] (epsiprantel)

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

12.5 mg

100 tablets

NADA #140-893, Approved by FDA

Pfizer



PRINCIPAL DISPLAY PANEL - 50 25 mg Tablet Bottle Label

Cestex[®]
(epsiprantel)

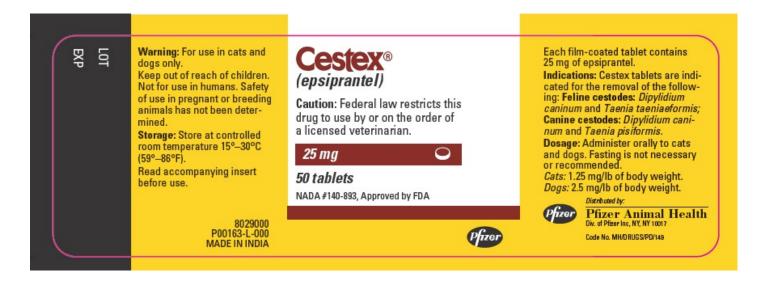
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

25 mg

50 tablets

NADA #140-893, Approved by FDA

Pfizer



PRINCIPAL DISPLAY PANEL - 100 25 mg Tablet Bottle Label

Ces tex® (epsiprantel)

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

25 mg

100 tablets

NADA #140-893, Approved by FDA

Pfizer



Cestex[®] (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

Pfizer



PRINCIPAL DISPLAY PANEL - 50 50 mg Tablet Bottle Label

Cestex® (epsiprantel)

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

50 mg

50 tablets

NADA #140-893, Approved by FDA

Pfizer



PRINCIPAL DISPLAY PANEL - 25 100 mg Tablet Bottle Label

Cestex® (epsiprantel)

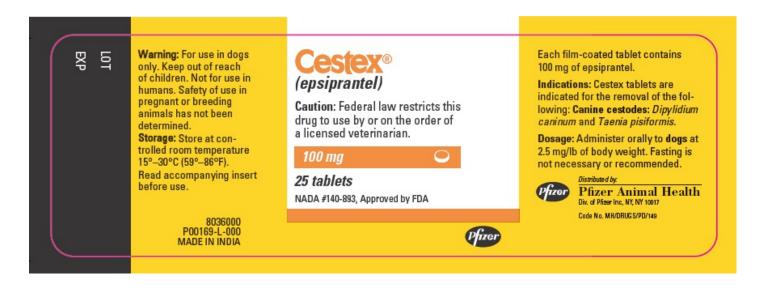
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

100 mg

25 tablets

NADA #140-893, Approved by FDA

Pfizer



PRINCIPAL DISPLAY PANEL - 50 100 mg Tablet Bottle Label

Ces tex® (epsiprantel)

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

100 mg

50 tablets

NADA #140-893, Approved by FDA

Pfizer



CESTEX

epsiprantel tablet, film coated

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG LABEL	Item Code (Source)	NDC:61106- 8032
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
epsiprantel (epsiprantel)	epsiprantel	12.5 mg	

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:61106-8032-3	50 in 1 BOTTLE			
2	NDC:61106-8032-2	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 LABEL	Item Code (Source)	NDC:61106- 8033
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
epsiprantel (epsiprantel)	epsiprantel	25 mg	

Product Characteristics				
Color	BROWN	Score	2 pieces	
Shape	ROUND (bi-convex)	Size	8 mm	
Flavor		Imprint Code	220	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:61106-8033-4	50 in 1 BOTTLE			
2	NDC:61106-8033-3	100 in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140893	12/0 1/19 8 9	

CESTEX

epsiprantel tablet, film coated

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG LABEL	Item Code (Source)	NDC:61106- 8034
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
epsiprantel (epsiprantel)	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:61106-8034-1	25 in 1 BOTTLE		
2 NDC:61106-8034-2	50 in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA140893	12/0 1/19 8 9		

CESTEX

epsiprantel tablet, film coated

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG LABEL	Item Code (Source)	NDC:61106- 8035
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
epsiprantel (epsiprantel)	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:61106-8035-6	25 in 1 BOTTLE		
2	NDC:61106-8035-5	50 in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA140893	12/0 1/19 8 9		

Labeler - Pfizer Animal Health (039055157)

Registrant - Pfizer Inc. (943955690)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pfizer Animal Health		039055157	MANUFACTURE	

Establishment			
Name	Address	ID/FEI	Business Operations
Emcure Pharmaceuticals Ltd., India, Pune		862602830	MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
UQUIFA MEXICO S.A. DE. C.V.		810105874	API MANUFACTURE

Revised: 10/2012 Pfizer Animal Health