

ACEPROMAZINE MALEATE- acepromazine maleate tablet
ZYVET ANIMAL HEALTH INC.

Acepromazine Maleate Tablets

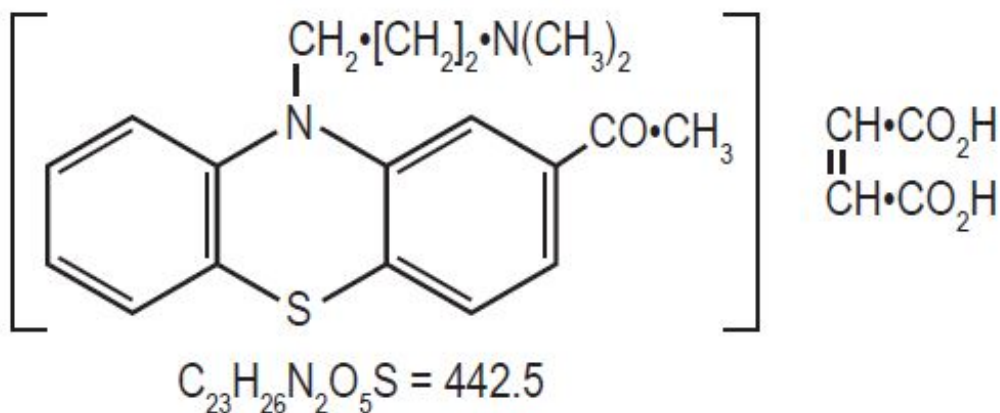
For use in dogs only.

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

Description: Acepromazine maleate, a potent neuroleptic agent with a low order of toxicity, is of particular value in the tranquilization of dogs. Its rapid action and lack of hypnotic effect are added advantages.

Chemistry: 2-acetyl-10-(3-dimethylaminopropyl) phenothiazine hydrogen maleate.

Acepromazine Maleate



Mode of Action: Acepromazine maleate has a depressant effect on the central nervous system and therefore causes sedation, muscular relaxation and a reduction in spontaneous activity. It acts rapidly, exerting a prompt and pronounced calming effect. It is an effective preanesthetic agent and lowers the dosage requirement of general anesthetics.

Indications: As an aid in tranquilization and as a preanesthetic agent in dogs.

Acepromazine Maleate Tablets can be used as an aid in controlling intractable animals during examination, treatment, grooming, x-ray and minor surgical procedures.

Dosage and Administration: Dogs: 0.25-1.0 mg/lb of body weight. Dosage may be repeated as required.

Animal Safety: Acute and chronic toxicity studies have shown a very low order of toxicity for acepromazine maleate.

A safety study using elevated dosages of acepromazine maleate demonstrated no adverse reactions even when administered at three times the upper limit of the recommended daily dosage (3.0 mg/lb body weight). The clinical observation for this high dosage was mild depression which disappeared in most dogs 24 hours after termination of dosing.

The only occurrence of adverse reaction during numerous clinical trials was a very mild respiratory distress (reverse sneeze) which was transient in nature and had no effect on the desired action of the drug.

Contraindications: Phenothiazines may potentiate the toxicity of organophosphates. Therefore, do not use acepromazine maleate to control tremors associated with organic phosphate poisoning.

Do not use in conjunction with organophosphorus vermifuges or ectoparasiticides, including flea collars.

Do not use with procaine hydrochloride.

Warning: Do not use in animals intended for human consumption.

Keep Acepromazine Maleate Tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Precautions: Tranquilizers are potent central nervous system depressants, and they can cause marked sedation with suppression of the sympathetic nervous system. Tranquilizers can produce prolonged depression or motor restlessness when given in excessive amounts or when given to sensitive animals.

Tranquilizers are additive in action to the actions of other depressants and will potentiate general anesthesia. Tranquilizers should be administered in smaller doses and with greater care during general anesthesia and also to animals exhibiting symptoms of stress, debilitation, cardiac disease, sympathetic blockade, hypovolemia or shock. Acepromazine, like other phenothiazine derivatives, is detoxified in the liver; therefore, it should be used with caution on animals with a previous history of liver dysfunction or leukopenia.

Epinephrine is contraindicated for treatment of acute hypotension produced by phenothiazine-derivative tranquilizers since further depression of blood pressure can occur.

Phenothiazines should be used with caution when followed by epidural anesthetic procedures because they may potentiate the arterial hypotensive effects of local anesthetics.

Adverse Reactions: A few rare but serious occurrences of idiosyncratic reactions to

acepromazine may occur in dogs following oral or parenteral administration. These potentially serious adverse reactions include behavioral disorders in dogs such as aggression, biting/chewing, and nervousness.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact ZyVet Animal Health Inc. at 1-877-779-9838.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

Storage: Store at 20° - 25°C (68° - 77°F). Excursions permitted to 40°C (104°F).

How Supplied: Acepromazine Maleate Tablets are available in 10 and 25 mg quarter-scored tablets and are supplied in bottles containing 100 and 500 tablets.

NDC 86117-049-07 - 10 mg - 100 tablets

NDC 86117-049-12 - 10 mg - 500 tablets

NDC 86117-050-07 - 25 mg - 100 tablets

NDC 86117-050-12 - 25 mg - 500 tablets

Approved by FDA under ANADA # 200-757

Manufactured by:

Zydus Animal Health and Investments Limited, Ahmedabad, India.

Distributed by:

ZyVet Animal Health Inc.
Pennington, NJ 08534

Principal Display Panel - Bottle Label, 10 mg - 100 Tablets

NDC 86117-049-07

Acepromazine

Maleate Tablets

10 mg

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Approved by FDA under ANADA # 200-757

Net Contents:

100 Tablets



Principal Display Panel - Bottle Label, 10 mg - 500 Tablets

NDC 86117-049-12

Acepromazine Maleate Tablets

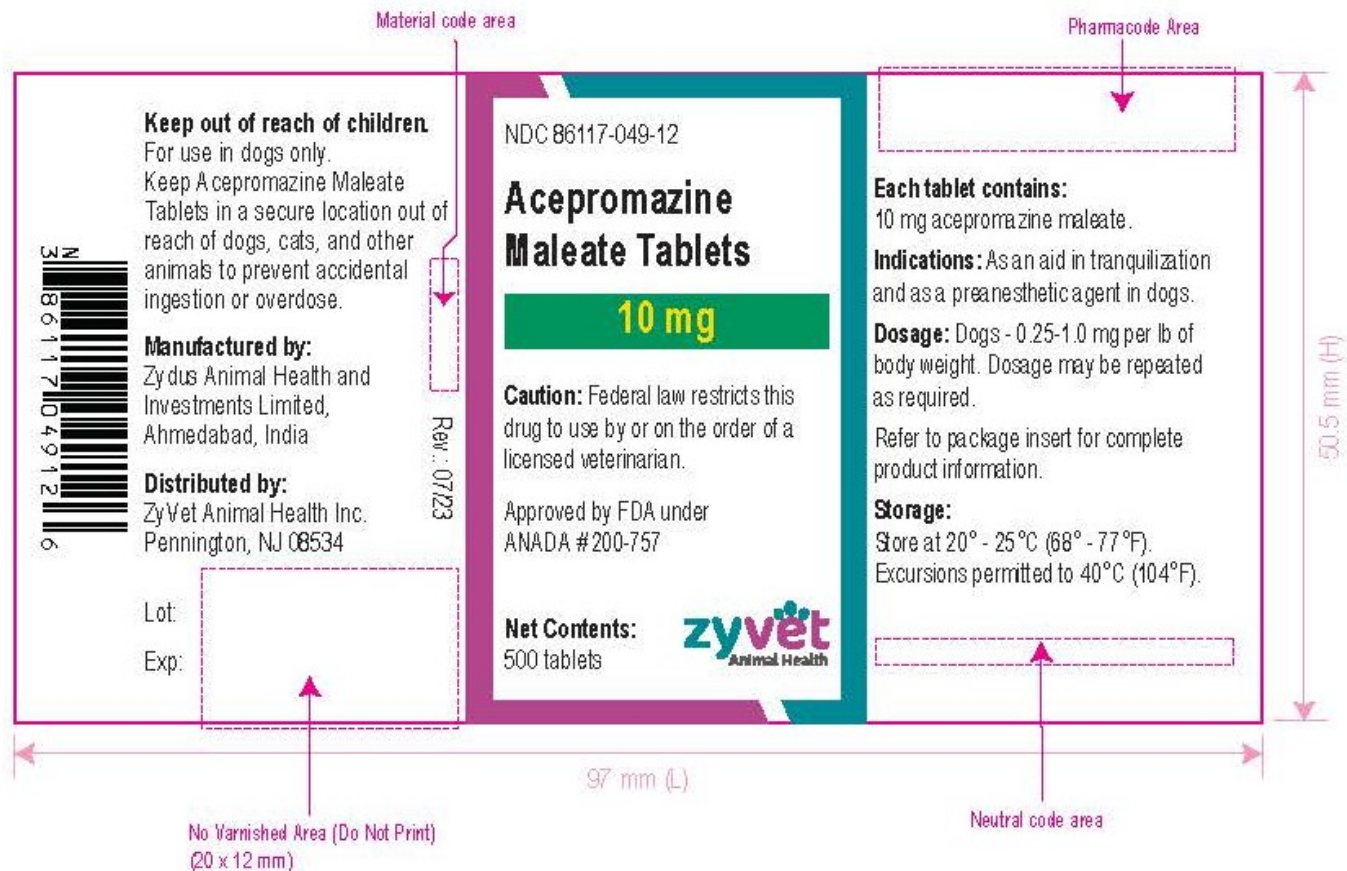
10 mg

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

Approved by FDA under ANADA # 200-757

Net Contents:

500 Tablets



Principal Display Panel - Bottle Label, 25 mg - 100 Tablets

NDC 86117-050-07

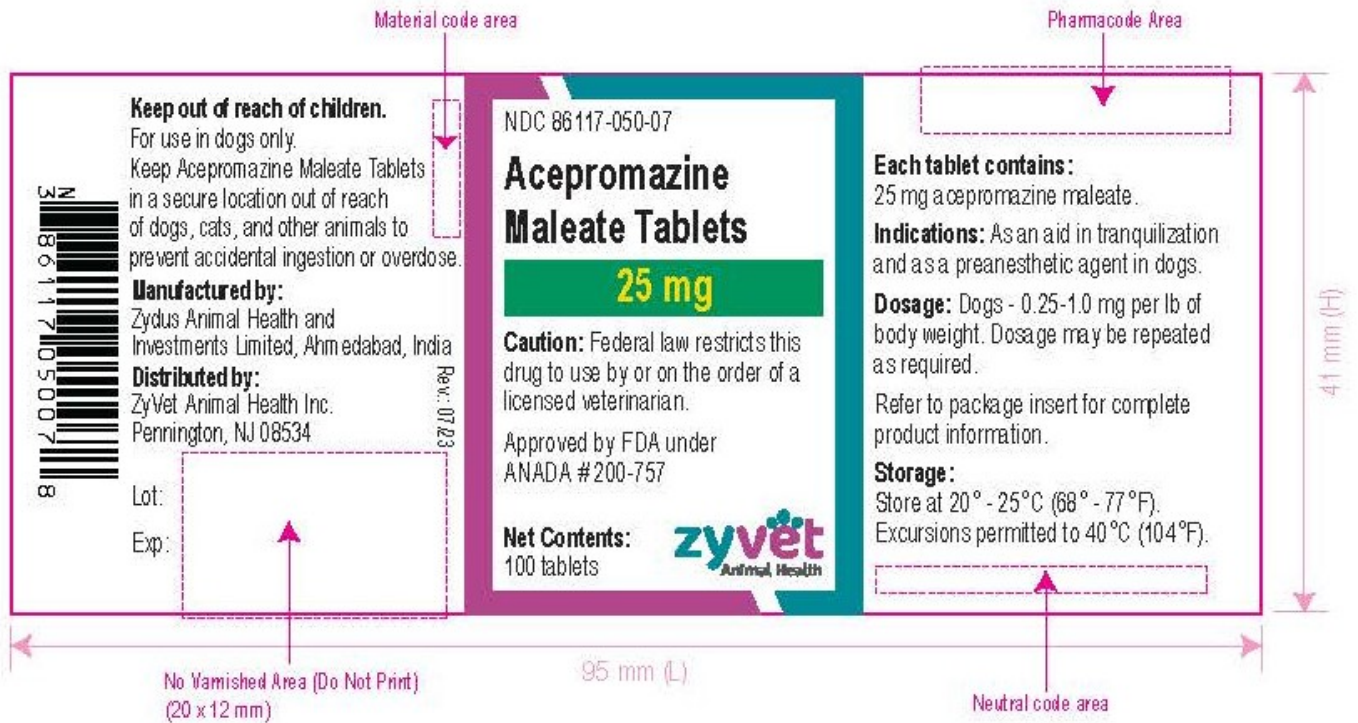
Acepromazine Maleate Tablets

25 mg

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Net Contents:

100 Tablets



Principal Display Panel - Bottle Label, 25 mg - 500 Tablets

NDC 86117-050-12

Acepromazine Maleate Tablets

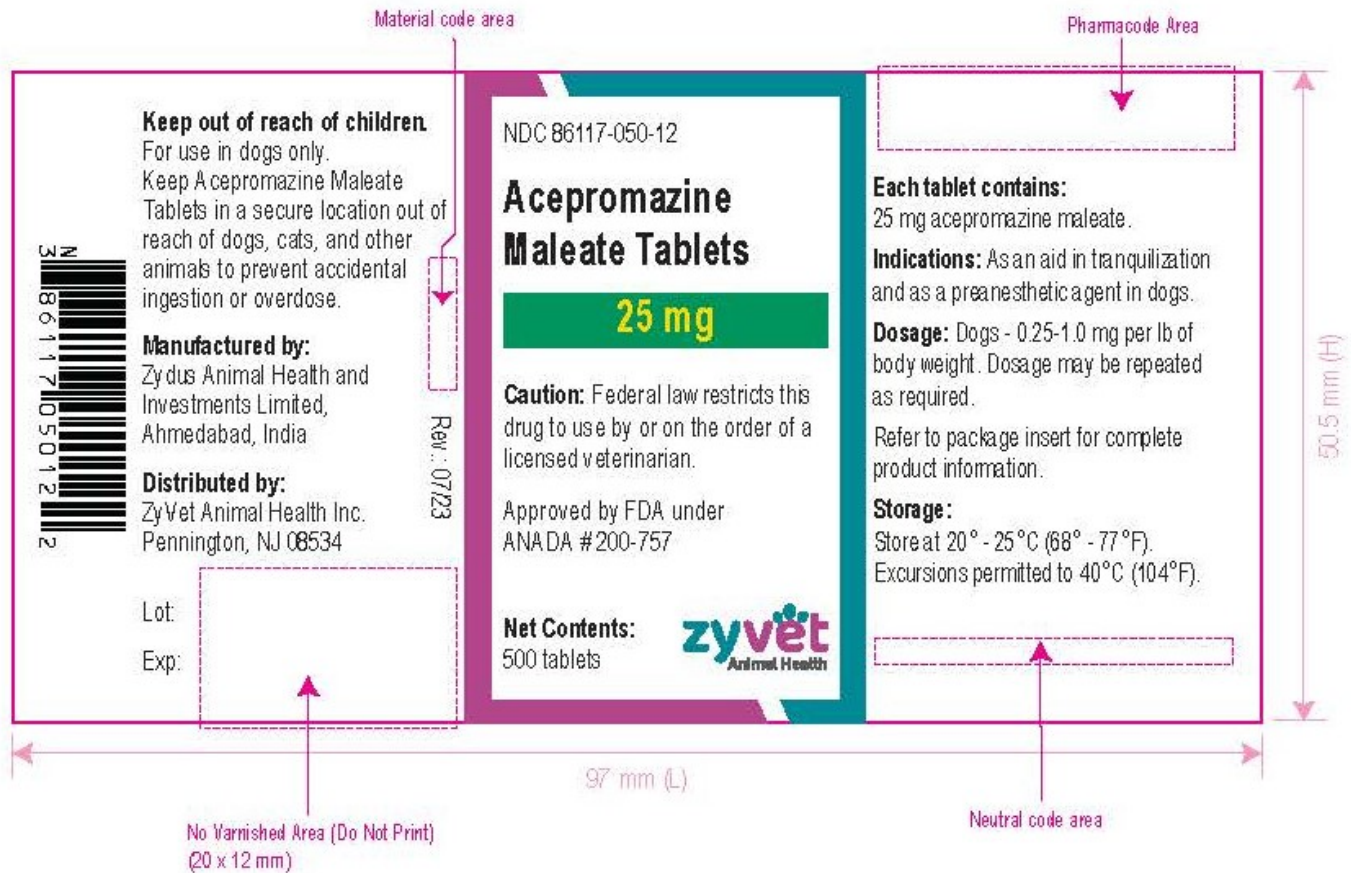
25 mg

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Approved by FDA under ANADA # 200-757

Net Contents:

500 Tablets



ACEPROMAZINE MALEATE

acepromazine maleate tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:86117-049
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACEPROMAZINE MALEATE (UNII: 37862HP2OM) (ACEPROMAZINE - UNII:54EJ303FOR)	ACEPROMAZINE MALEATE	10 mg

Product Characteristics

Color	PINK (Light pink to peach)	Score	4 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	35;U
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:86117-049-07	100 in 1 BOTTLE		
2	NDC:86117-049-12	500 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200757	12/01/2023	

ACEPROMAZINE MALEATE				
acepromazine maleate tablet				
Product Information				
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:86117-050	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ACEPROMAZINE MALEATE (UNII: 37862HP2OM) (ACEPROMAZINE - UNII:54EJ303FOR)	ACEPROMAZINE MALEATE	25 mg	
Product Characteristics				
Color	yellow	Score	4 pieces	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	37;U	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86117-050-07	100 in 1 BOTTLE		
2	NDC:86117-050-12	500 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANADA	ANADA200757	12/01/2023		

Labeler - ZYVET ANIMAL HEALTH INC. (117047560)

Registrant - ZYVET ANIMAL HEALTH INC. (117047560)

Revised: 11/2023

ZYVET ANIMAL HEALTH INC.