

**ACEPROMAZINE MALEATE- acepromazine maleate tablet
Aspen Veterinary Resources®, LTD.**

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.

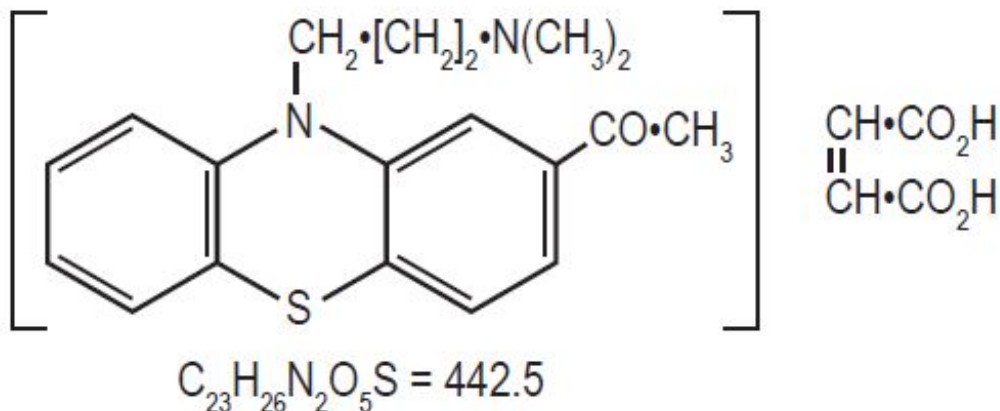
Description:

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 the manufacturer 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 46066-138-32 – 10 mg – 100 tablets

NDC 46066-138-34 – 10 mg – 500 tablets

NDC 46066-139-32 – 25 mg – 100 tablets

NDC 46066-139-34 – 25 mg – 500 tablets

Approved by FDA under ANADA # 200-757

GUJ/DRUGS/G/25/2354

Manufactured For:

Aspen Veterinary Resources®, LTD.

Liberty, MO 64068

pivetavet.com

Made in India

P0202.ZVP

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

NDC: 46066-138-32

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:

100 tablets

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

Manufactured for:
Aspen Veterinary Resources®, LTD.
Liberty, MO 64068
pivetalvet.com | P0202.ZVP Rev. 09/24
Made in India

Lot:
Exp:

2098760

NDC 46066-138-32

**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:
100 tablets

Pivotal.

Each tablet contains:
10 mg acepromazine maleate.
Indications: As an aid in tranquilization
and as a preanesthetic agent in dogs.
Dosage: Dogs - 0.25-1.0 mg per lb of
body weight. Dosage may be repeated
as required.
Refer to package insert for complete
product information.
Storage:
Store at 20° - 25°C (68° - 77°F).
Excursions permitted to 40°C (104°F).

GUJ/DRUGS/G/25/2354

95 mm (L)

41 mm (H)

No Varnished Area (Do Not Print)
(20 x 12 mm)

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

NDC: 46066-138-34

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

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

2098761

NDC 46066-138-34

ACEPROMAZINE MALEATE TABLETS

10 mg

Each tablet contains:
10 mg acepromazine maleate.

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

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

Refer to package insert for complete product information.

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

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

Manufactured for:
Aspen Veterinary Resources®, LTD.
Liberty, MO 64068
pivotalvet.com | P0203.ZVP Rev. 09/24
Made in India

0 99355 04061 8

Lot:
Exp:
No Varnished Area (Do Not Print) (20 x 12 mm)

Pivotal. GUJ/DRUGS/G/25/2354

97 mm (L)

50.5 mm (H)

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

NDC: 46066-139-32

Acepromazine Maleate Tablets

25 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:

100 tablets

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

Manufactured for:
Aspen Veterinary Resources®, LTD.
Liberty, MO 64068
pivotalvet.com | P0204.ZVP Rev. 09/24

Made in India

Lot:
Exp:

2098762

NDC 46066-139-32

ACEPROMAZINE MALEATE TABLETS

25 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:
100 tablets

Pivotal.

Each tablet contains:
25 mg acepromazine maleate.

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

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

Refer to package insert for complete product information.

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

GUJ/DRUGS/G/25/2354

41 mm (H)

95 mm (L)

No Varnished Area (Do Not Print)
(20 x 12 mm)

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

NDC: 46066-139-34

Acepromazine Maleate Tablets

25 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

Keep out of reach of children.
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2098763

NDC 46066-139-34

ACEPROMAZINE MALEATE TABLETS

25 mg

Each tablet contains:
25 mg acepromazine maleate.

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

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Refer to package insert for complete product information.

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

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

Pivotal. GUJ/DRUGS/G/25/2354

Manufactured for:
Aspen Veterinary Resources®, LTD.
Liberty, MO 64068
pivotalvet.com | P0205.ZVP Rev. 09/24
Made in India

0993551040458

Lot:

Exp:

97 mm (L)

50.5 mm (H)

No Varnished Area (Do Not Print)
(20 x 12 mm)

ACEPROMAZINE MALEATE

acepromazine maleate tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:46066-138
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACEPROMAZINE MALEATE (UNII: 37862HP20M) (ACEPROMAZINE - UNII:54EJ303F0R)	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
1	NDC:46066-138-32	100 in 1 BOTTLE		

2 NDC:46066-138-34 500 in 1 BOTTLE

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200757	01/16/2025	

ACEPROMAZINE MALEATE

acepromazine maleate tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:46066-139
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:46066-139-32	100 in 1 BOTTLE		
2	NDC:46066-139-34	500 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200757	01/16/2025	

Labeler - Aspen Veterinary Resources®, LTD. (627265361)

Registrant - ZYVET ANIMAL HEALTH INC. (117047560)

