PROMACE- acepromazine maleate tablet
Boehringer Ingelheim Vetmedica, Inc.

PromAce® Tablets
AcepromazineMaleate Tablets, USP

NADA 117-532, Approved by FDA

For use in dogs only.

Caution

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

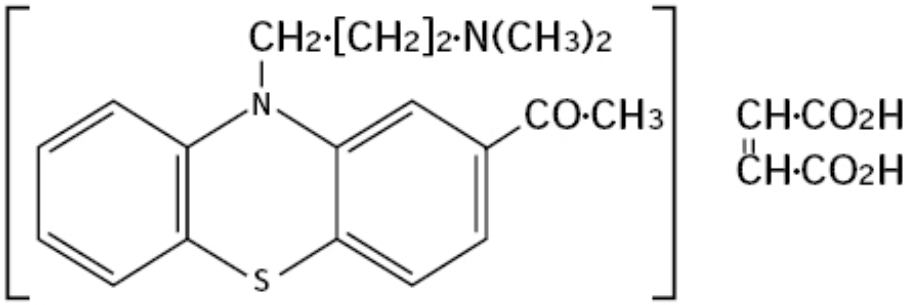
Description

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



$C_{23}H_{26}N_2O_5S = 442.5$

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. PromAce 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.

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 reactions, to obtain a Material Safety Data Sheet or for technical assistance, call 1-866-638-2226.

Storage

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (between 59° and 86°F).

How Supplied

PromAce (acepromazine maleate) Tablets are available in 10 and 25 mg quarter-scored tablets and are supplied in bottles containing 100 and 500 tablets.

NDC 0010-6703-01 – 10 mg – 100 tablets

NDC 0010-6703-02 – 10 mg – 500 tablets

NDC 0010-6704-01 – 25 mg – 100 tablets

NDC 0010-6704-02 – 25 mg – 500 tablets

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670203-02

83651793

83651971, R.0

Revised 06/2012

Bottle Label, 25 mg, 500 count

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 bodyweight. Dosage may be repeated as required.

Refer to folded package insert attached to this container for complete product information.

Storage: Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (between 59° and 86°F).

Keep out of reach of children. For use in dogs only.

Manufactured for:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.

Boehringer Ingelheim

670203-02
83651793
83651971, R.0

PROMACE

acepromazine maleate tablet

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:0010-6704
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACEPROMAZINE MALEATE (UNII: 37862HP2OM) (ACEPROMAZINE - UNII:54EJ303F0R)	ACEPROMAZINE MALEATE	25 mg

Product Characteristics

Color	YELLOW	**Score**	4 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	0221
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-6704-01	100 in 1 BOTTLE, PLASTIC		
2	NDC:0010-6704-02	500 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA117532	02/13/2013	

Labeler - Boehringer Ingelheim Vetmedica, Inc. (007134091)

Revised: 2/2013

Boehringer Ingelheim Vetmedica, Inc.