

HFA-305

Date of Approval: MAR 25 2003

## **FREEDOM OF INFORMATION (FOI) SUMMARY**

**Acepromazine Maleate Injection  
10 mg/mL**

**Tranquilizer for use in dogs, cats, and horses**

**ANADA 200-319**

**Phoenix Scientific, Inc.**

**3915 South 48<sup>th</sup> Street Terrace**

**St. Joseph, MO 64503**

FOIS |

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

- a. ANADA Number: 200-319
- b. SPONSOR: Phoenix Scientific, Inc.  
3915 South 48<sup>th</sup> Street Terrace  
St. Joseph, MO 64503  
  
Drug Labeler Code: 059130
- c. Established Name: Acepromazine Maleate Injection
- d. Proprietary Name: Acepromazine Maleate Injection
- e. Dosage Form: Injection (solution)
- f. How Supplied: 50 mL glass bottles
- g. How Dispensed:  $\mathcal{R}$
- h. Amount of Active Ingredients: 10 mg acepromazine maleate/mL
- i. Route of Administration: Intravenous, Intramuscular, or Subcutaneous Injection
- j. Species: Canine, Feline and Equine
- k. Labeled Dosage:

The dosage should be individualized, depending upon the degree of tranquilization required. As a general rule, the dosage requirement in mg/lb of body weight decreases as the weight of the animal increases. Acepromazine Maleate Injection may be given intravenously, intramuscularly or subcutaneously. The following schedule may be used as a guide to IV, IM or SC injections:

**Dogs:** 0.25-0.5 mg/lb of body weight

**Cats:** 0.5-1 mg/lb of body weight

**Horses:** 2-4 mg/100lb of body weight

IV doses should be administered slowly, and a period of at least 15 minutes should be allowed for the drug to take full effect.

**I. Pharmacological Category:**

Anesthetic

**m. Indications For Use:**

**Dogs and Cats:** Acepromazine Maleate Injection can be used as an aid in controlling intractable animals during examination, treatment, grooming, x-ray and minor surgical procedures; to alleviate itching as a result of skin irritation; as an antiemetic to control vomiting associated with motion sickness.

Acepromazine Maleate Injection is particularly useful as a preanesthetic agent (1) to enhance and prolong the effects of barbiturates, thus reducing the requirements for general anesthesia; (2) as an adjunct to surgery under local anesthesia.

**Horses:** Acepromazine Maleate Injection can be used as an aid in controlling fractious animals during examination, treatment, loading and transportation. Particularly useful when used in conjunction with local anesthesia for firing, castration, neurectomy, removal of skin tumors, ocular surgery and applying casts.

**n. Pioneer Product**

PromAce<sup>®</sup> Injectable NADA 015-030  
(Fort Dodge Animal Health, Inc.)

## 2. **TARGET ANIMAL SAFETY and DRUG EFFECTIVENESS**

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement of conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter, Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study for Acepromazine Maleate Injection on October 20, 1997 (JINAD 010-181 R0000). The generic and pioneer products contain the same active and inactive ingredients in the same concentrations.

## 3. **HUMAN SAFETY:**

None required as Acepromazine Maleate Injection is labeled for use in dogs, cats, and horses. The labeling also contains the statement, "Warning: Not for use in animals intended for food".

### **Human Safety Relative to Possession, Handling and Administration:**

Labeling contains adequate caution/warning statements.

## 4. **AGENCY CONCLUSIONS:**

This Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal Food, Drug, and Cosmetic (FFD&C) Act satisfies the requirements of section 512(n) of the act and demonstrates that Acepromazine Maleate Injection, when used under its proposed conditions of use, is safe and effective for the labeled indications.

**5. Attachments:**

1. **Generic Labeling: Facsimile package labeling for generic product, 50 ml bottle, and package insert.**
2. **Pioneer Labeling: Bottle Label, Package Insert, Printed Chipboard**

**COMPOSITION:** Each mL of sterile aqueous solution contains:

**Acepromazine** [10-[3-(dimethyl-amino) propyl] phenothiazin-2-yl-methyl ketone], Maleate 10 mg, sodium citrate 0.36%, citric acid 0.075%, benzyl alcohol 1% and water for injection, USP, qs.

600097      Iss. 11-01

Manufactured by  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

NDC 69130-708-11

**NET CONTENTS: 50 mL**  
**Acepromazine Maleate Injection**  
**10 mg/mL**

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

**FOR ANIMAL USE ONLY**  
**KEEP OUT OF REACH OF CHILDREN**  
ANADA 200-319, Approved by FDA

**AmTech**  
Group, Inc.

For Intravenous, Intramuscular or Subcutaneous Injection.

**READ PACKAGE INSERT.**

**USUAL DOSAGE:** Dogs - 0.25 mg up to 0.5 mg/lb of body weight. Cats - 0.5 mg up to 1 mg/lb of body weight. Horses - 2 mg up to 4 mg/100 lbs of body weight.

Store at controlled room temperature between 15°C and 30°C (59° and 86°F).

TAKE TIME  **OBSERVE LABEL DIRECTIONS**

Lot No.  
Exp. Date

**COMPOSITION:** Each mL of sterile aqueous solution contains:

**Acepromazine** [10-[3-(dimethyl-amino) propyl] phenothiazin-2-yl-methyl ketone], Maleate 10 mg, sodium citrate 0.36%, citric acid 0.075%, benzyl alcohol 1% and water for injection, USP, qs.

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Store at controlled room temperature between 15°C and 30°C (59° and 86°F).

TAKE TIME  **OBSERVE LABEL DIRECTIONS**

Lot No.  
Exp. Date

200%

**CUSTOMER PDF PROOF • CHECK CAREFULLY!**

Customer: Phoenix Scientific      P.O. #: Christina

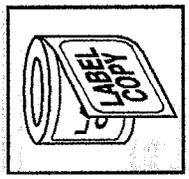
CVREL #: 24228 (In)      Date Sent: 1/04/02 03/16/02

LABEL: Acepromazine Maleate Injection      UNWIND #: 4

SIZE: 1.5625" x 4.25"

VARNISH:  YES       PATTERN       FLOOD  
 NO

COLORS: black      1797 red      water varn.



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Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_

ANADA 200-319, Approved by FDA

## ACEPROMAZINE MALEATE INJECTION

### CAUTION

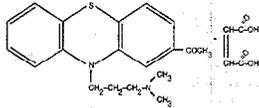
Federal law restricts this drug to use by or on the order of a licensed veterinarian.

### DESCRIPTION

Acepromazine Maleate Injection, a potent neuroleptic agent with a low order of toxicity, is of particular value in the tranquilization of dogs, cats and horses. Its rapid action and lack of hypnotic effect are added advantages. According to Baker,<sup>1</sup> the scope of possible applications for this compound in veterinary practice is only limited by the imagination of the practitioner.

### CHEMISTRY

Acepromazine [10-[3-(dimethylamino)propyl] phenothiazin-2-yl-methyl ketone] Maleate has the following chemical structure:



### ACTIONS

Acepromazine Maleate Injection 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.

### INDICATIONS

**Dogs and Cats:** Acepromazine Maleate Injection can be used as an aid in controlling intractable animals during examination, treatment, grooming, x-ray and minor surgical procedures; to alleviate itching as a result of skin irritation; as an antiemetic to control vomiting associated with motion sickness.

Acepromazine Maleate Injection is particularly useful as a preanesthetic agent (1) to enhance and prolong the effects of barbiturates, thus reducing the requirements for general anesthesia; (2) as an adjunct to surgery under local anesthesia.

**Horses:** Acepromazine Maleate Injection can be used as an aid in controlling fractious animals during examination, treatment, loading and transportation. Particularly useful when used in conjunction with local anesthesia for firing, castration, neutrectomy, removal of skin tumors, ocular surgery and applying casts.

### CONTRAINDICATIONS

Phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride. Therefore, do not use Acepromazine Maleate Injection 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

Not for use in animals intended for food.

### 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 Maleate Injection, like other phenothiazine derivatives, is detoxified in the liver; therefore, it should be used with caution in animals with a previous history of liver dysfunction or leukopenia.

Hypotension can occur after rapid intravenous injection causing cardiovascular collapse.

Epinephrine is contraindicated for treatment of acute hypotension produced by phenothiazine-derivative tranquilizers since further depression of blood pressure can occur. Other pressor amines, such as norepinephrine or phenylephrine, are the drugs of choice.

In horses, paralysis of the retractor penis muscle has been associated with the use of phenothiazine-derivative tranquilizers. Such cases have occurred following the use of Acepromazine Maleate Injection. This risk should be duly considered prior to the administration of Acepromazine Maleate Injection to male horses (castrated and uncastrated). When given, the dosage should be carefully limited to the minimum necessary for the desired effect. At the time of tranquilization, it is

not possible to differentiate between reversible protrusion of the penis (a normal clinical sign of narcosis) and the irreversible paralysis of the retractor muscle. The cause of this side reaction has not been determined. It has been postulated that such paralysis may occur when a tranquilizer is used in conjunction with testosterone (or in stallions).

Accidental intracarotid injection in horses can produce clinical signs ranging from disorientation to convulsive seizures and death.

### ADMINISTRATION AND DOSAGE

The dosage should be individualized, depending upon the degree of tranquilization required. As a general rule, the dosage requirement in mg/lb of body weight decreases as the weight of the animal increases.

Acepromazine Maleate Injection may be given intravenously, intramuscularly or subcutaneously. The following schedule may be used as a guide to IV, IM or SC injections:

**Dogs:** 0.25-0.5 mg/lb of body weight

**Cats:** 0.5-1 mg/lb of body weight

**Horses:** 2-4 mg/100 lb of body weight

IV doses should be administered slowly, and a period of at least 15 minutes should be allowed for the drug to take full effect.

### HOW SUPPLIED

Each mL contains 10 mg acepromazine maleate. (Also contains sodium citrate 0.38%, citric acid 0.075%, benzyl alcohol 1% and Water for Injection, USP) in 50 mL vials.

Store at controlled room temperature between 15° and 30°C (59° and 86°F).

### TOXICOLOGY

Acute and chronic toxicity studies have shown a very low order of toxicity.

**Acute Toxicity:** The LD<sub>50</sub> dose of Acepromazine Maleate Injection in mice was determined by means of a probit transformation with the following results:<sup>2</sup>

Intravenous route — 61.37 mg/kg

Oral route — 256.8 mg/kg

Subcutaneous route — 130.5 mg/kg

**Chronic toxicity:** Tests<sup>3</sup> in rats revealed no deleterious effects on renal or hepatic function or on hemopoietic activity. In several groups of two male and two female beagle hounds treated for six months with daily oral doses of 20 to 40 mg/kg, no untoward effects were encountered. Hematologic studies and urinalysis gave values within normal limits. Another group of four dogs, given gradually increasing oral doses up to a level of 220 mg/kg daily and reaching a total daily dose of 2.2 g per dog, showed some signs of pulmonary edema and hyperemia of the internal organs, but no animal died.

When administered intramuscularly, Acepromazine Maleate Injection causes a brief sensation of stinging comparable with that observed with other phenothiazine tranquilizers.

### CLINICAL DATA

Controlled clinical studies in the United States and Canada have demonstrated the effectiveness and safety of Acepromazine Maleate Injection as a tranquilizer.

Good to excellent results were reported<sup>4,5</sup> in dogs, cats and horses given Acepromazine Maleate Injection for restraint during examination, treatment and minor surgery and for preanesthetic sedation. In dogs, the drug reportedly helps control convulsions associated with distemper.

In both dogs and cats, good to excellent results were obtained<sup>4</sup> when Acepromazine Maleate Tablets were used to control nervousness, excessive vocalization, neurotic and excitable behavior, vomiting associated with motion sickness, coughing and itching caused by dermatitis.

In horses, Bauman<sup>6</sup> had good results using the drug as an aid in the control of painful spasms due to colic.

Other practitioners<sup>7,8</sup> found the drug useful as a preanesthetic sedative for nervous or aggressive horses, but it had to be administered while the animals were quiet and not in an excited state. In a trial<sup>9</sup> on more than 200 horses with a wide variety of disorders, Acepromazine Maleate Injection proved to be both effective and safe.

### REFERENCES

1. Baker, J.M.: Paper presented at the Ontario Veterinary Association meeting, held in Toronto, Canada, 1958.
2. Pharmacology Reports, ClinByla Laboratories, Paris, France.
3. Stegen, M.G.: Pharmacology Report, Ayerst Laboratories, 1958.
4. Veterinary Medical Records, Ayerst Laboratories.
5. Foley, J.T.: Clinical Reports to Ayerst Laboratories, 1963.
6. Bauman, W.G.: Clinical Reports to Ayerst Laboratories, 1963.
7. Ford, R.W.: in Equine Panel Report, *Mod. Vet. Pract.* 40:45 (Nov. 1) 1959.
8. Baldwin, R.: in Equine Panel Report, *Mod. Vet. Pract.* 40:46 (Nov. 1) 1959.
9. Dunkin, T.E.: Clinical Reports to Ayerst Laboratories, 1963.

600097

Iss. 11-01

Manufactured by  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

## CUSTOMER PDF PROOF • CHECK CAREFULLY!

Customer: Phoenix Scientific P.O. #: Christina  
CYREL #: 24243 (In) Date Sent: 11/29/01 12/7/01 12/17/01 12/27/01 01/04/02 03/15/02

LABEL: Acepromazine Maleate Injection

UNWIND #: \_\_\_\_\_

SIZE: 3.5" x 9.0"

VARNISH:  YES  PATTERN  FLOOD  
 NO

COLORS: black 306 blue

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Approved by: \_\_\_\_\_ Date approved: \_\_\_\_\_



**FORT DODGE**<sup>®</sup>

**PromAce<sup>®</sup> Injectable**  
**ACEPROMAZINE MALEATE INJECTION, USP**  
**PromAce<sup>®</sup> Tablets**  
**ACEPROMAZINE MALEATE, USP**

NADA 15-030, Approved by FDA  
 NADA 32-702, Approved by FDA

**CAUTION**

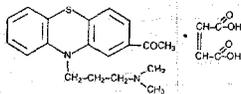
Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION**

PROMACE (acepromazine maleate, USP), a potent neuroleptic agent with a low order of toxicity, is of particular value in the tranquilization of dogs, cats and horses. Its rapid action and lack of hypnotic effect are added advantages. According to Baker,<sup>1</sup> the scope of possible applications for this compound in veterinary practice is only limited by the imagination of the practitioner.

**CHEMISTRY**

Acepromazine [10-[3-(dimethylamino) propyl] phenothiazin-2-yl-methyl ketone] Maleate, USP has the following chemical structure:



**ACTIONS**

PROMACE 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.

**INDICATIONS**

**Dogs and Cats:** PROMACE Injectable and Tablets can be used as an aid in controlling intractable animals during examination, treatment, grooming, x-ray and minor surgical procedures; to alleviate itching as a result of skin irritation; as an antiemetic to control vomiting associated with motion sickness.

PROMACE Injectable is particularly useful as a preanesthetic agent (1) to enhance and prolong the effects of barbiturates, thus reducing the requirements for general anesthesia; (2) as an adjunct to surgery under local anesthesia.

**Horses:** PROMACE Injectable can be used as an aid in controlling fractious animals during examination, treatment, loading and transportation. Particularly useful when used in conjunction with

local anesthesia for firing, castration, neutrectomy, removal of skin tumors, ocular surgery and applying casts.

**CONTRAINDICATIONS**

Phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride. Therefore, do not use PROMACE (acepromazine maleate, USP) 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**

Not for use in animals intended for food.

**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. PROMACE, like other phenothiazine derivatives, is detoxified in the liver; therefore, it should be used with caution in animals with a previous history of liver dysfunction or leukopenia.

Hypotension can occur after rapid intravenous injection causing cardiovascular collapse.

Epinephrine is contraindicated for treatment of acute hypotension produced by phenothiazine-derivative tranquilizers since further depression of blood pressure can occur. Other pressor amines, such as norepinephrine or phenylephrine, are the drugs of choice.

In horses, paralysis of the retractor penis muscle has been associated with the use of phenothiazine-derivative tranquilizers. Such cases have occurred following the use of PROMACE. This risk should be duly considered prior to the administration of PROMACE to male horses (castrated and uncastrated). When given, the dosage should be carefully limited to the minimum necessary for the desired effect. At the time of tranquilization, it is not possible to differentiate between reversible protrusion of the penis (a normal clinical sign of narcosis) and the irreversible paralysis of the retractor muscle. The cause of this side reaction has not been determined. It has been postulated that such paralysis may occur when a tranquilizer is used in conjunction with testosterone (or in stallions).

Accidental intracarotid injection in horses can produce clinical signs ranging from disorientation to convulsive seizures and death.

**CAUTION**

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.

#### ADMINISTRATION AND DOSAGE

The dosage should be individualized, depending upon the degree of tranquilization required. As a general rule, the dosage requirement in mg/lb of body weight decreases as the weight of the animal increases.

#### PROMACE (acepromazine maleate injection, USP) Injectable

May be given intravenously, intramuscularly or subcutaneously. The following schedule may be used as a guide to IV, IM or SC injections:

**Dogs:** 0.25–0.5 mg/lb of body weight

**Cats:** 0.5–1 mg/lb of body weight

**Horses:** 2–4 mg/100 lb of body weight

IV doses should be administered slowly, and a period of at least 15 minutes should be allowed for the drug to take full effect.

#### PROMACE (acepromazine maleate, USP) Tablets

**Dogs:** 0.25–1 mg/lb of body weight. Dosage may be repeated as required.

**Cats:** 0.5–1 mg/lb of body weight. Dosage may be repeated as required.

#### HOW SUPPLIED

Each mL contains 10 mg PROMACE (acepromazine maleate, USP). (Also contains sodium citrate 0.36%, citric acid 0.075%, benzyl alcohol 1% and Water for Injection, USP) in 50 mL vials.

Each light orange tablet contains 5 mg of PROMACE and is available in bottles of 100.

Each orange tablet contains 10 mg of PROMACE and is available in bottles of 100 and 500.

Each yellow tablet contains 25 mg of PROMACE and is available in bottles of 100 and 500.

NDC 0856-3020-01 — 10 mg/mL — 50 mL vial

NDC 0856-0040-01 — 5 mg — bottles of 100

NDC 0856-0070-01 — 10 mg — bottles of 100

NDC 0856-0070-02 — 10 mg — bottles of 500

NDC 0856-0100-01 — 25 mg — bottles of 100

NDC 0856-0100-02 — 25 mg — bottles of 500

Store at controlled room temperature 15° to 30°C (59° to 86°F).

#### TOXICOLOGY

Acute and chronic toxicity studies have shown a very low order of toxicity.

**Acute toxicity:** The LD<sub>50</sub> dose of PROMACE in mice was determined by means of a probit transformation with the following results:<sup>2</sup>

Intravenous route — 61.37 mg/kg

Subcutaneous route — 130.5 mg/kg

Oral route — 256.8 mg/kg

**Chronic toxicity:** Tests<sup>3</sup> in rats revealed no deleterious effects on renal or hepatic function or on hemopoietic activity. In several groups of two male and two female beagle hounds treated for six months with daily oral doses of 20 to 40 mg/kg, no untoward

effects were encountered. Hematologic studies and urinalysis gave values within normal limits. Another group of four dogs, given gradually increasing oral doses up to a level of 220 mg/kg daily and reaching a total daily dose of 2.2 g per dog, showed some signs of pulmonary edema and hyperemia of the internal organs, but no animal died.

When administered intramuscularly, PROMACE (acepromazine maleate, USP) causes a brief sensation of stinging comparable with that observed with other phenothiazine tranquilizers.

#### CLINICAL DATA

Controlled clinical studies in the United States and Canada have demonstrated the effectiveness and safety of PROMACE as a tranquilizer.

Good to excellent results were reported<sup>1,4,5</sup> in dogs, cats and horses given PROMACE Injectable for restraint during examination, treatment and minor surgery and for preanesthetic sedation. In dogs, the drug reportedly<sup>4</sup> helps control convulsions associated with distemper.

In both dogs and cats, good to excellent results were obtained<sup>4</sup> when PROMACE Tablets were used to control nervousness, excessive vocalization, neurotic and excitable behavior, vomiting associated with motion sickness, coughing and itching caused by dermatitis.

In horses, Bauman<sup>6</sup> had good results using the drug as an aid in the control of painful spasms due to colic.

Other practitioners<sup>7,8</sup> found the drug useful as a preanesthetic sedative for nervous or aggressive horses, but it had to be administered while the animals were quiet and not in an excited state. In a trial<sup>9</sup> on more than 200 horses with a wide variety of disorders, PROMACE Injectable proved to be both effective and safe.

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7. Ford, R.W.: in Equine Panel Report, *Mod. Vet. Pract.* 40:45 (Nov. 1) 1959.
8. Baldwin, R.: in Equine Panel Report, *Mod. Vet. Pract.* 40:46 (Nov. 1) 1959.
9. Dunkin, T.E.: Clinical Reports to Ayerst Laboratories, 1963.

Manufactured for

**Fort Dodge Animal Health**  
Fort Dodge, Iowa 50501 USA

by Fort Dodge Animal Health  
Fort Dodge, Iowa 50501 USA  
(Injection)

Ayerst Laboratories, Inc.  
Rouses Point, NY 12979  
(Tablets)

T0000

NDC 0856-3020-01

# PromAce<sup>®</sup> Injectable

ACEPROMAZINE MALEATE  
INJECTION, USP



A Sterile Solution for  
Intravenous, Intramuscular or  
Subcutaneous Injection

Multiple Dose Vial

Equivalent to 10 mg/mL  
Acepromazine Maleate, USP

## 50 mL

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

NADA 15-030, Approved by FDA



7 26287 10201 4



Fort Dodge Animal Health  
Fort Dodge, Iowa 50501 USA

8991  
91479  
0202F

8991  
0202F



SAMPLE

000008

NDC 0856-3020-01

**PromAce® Injectable**  
ACEPROMAZINE MALEATE INJECTION, USP

USUAL DOSAGE: Dogs — 0.25 mg up to 0.5 mg/lb of body weight. Cats — 0.5 mg up to 1 mg/lb of body weight. Horses — 2 mg up to 4 mg/100 lbs of body weight.

READ PACKAGE INSERT.

Store at controlled room temperature 15° to 30°C (59° to 86°F).

Acepromazine [10-[3-(dimethylamino) propyl] phenothiazin-2-yl-methyl ketone] Maleate, USP  
This sterile aqueous solution also contains sodium citrate 0.35%, citric acid 0.075%, benzyl alcohol 1% and water for injection, USP.

U.S. Pat. No. 3,330,625

**Fort Dodge Animal Health**  
Fort Dodge, Iowa 50501 USA



A Sterile Solution for  
Intravenous, Intramuscular or  
Subcutaneous Injection  
Equivalent to 10 mg/mL Acepromazine Maleate, USP

**50 mL**

CAUTION: Federal law restricts this drug to use by  
or on the order of a licensed veterinarian.  
NADA 15-285; Approved by FDA

Lct  
Exp.



H1020