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.

Refer to folded label attached to this container before using.

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

Acepromazine Maleate Injection

NDC 57319-447-04

10 mg/mL

A Sterile Solution for Intravenous, Intramuscular or Subcutaneous Injection.

ANADA 200-361, Approved by FDA

Net Contents: 50 mL

Acepromazine [10-[3-(dimethylamino) propyl] phenothiazin-2-yl-methyl ketone] Maleate, USP

This sterile aqueous solution also contains sodium citrate 0.36%, citric acid 0.075%, benzyl alcohol 1% and water for injection, USP.

67008L-03-0408

Manufactured By: Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.
Actions: Acepromazine has a depressant action on the central nervous system and is a highly potent neuroleptic. It exerts a sedative effect, reducing reflex movements, and producing cataleptic states. It also reduces spontaneous activity. Its administration is particularly useful as a preanesthetic agent (1) to enhance the immobilization effect of other depressants and (2) to prolong the effects of general anesthetics.

Requirements in mg/lb of body weight generally vary with body weight and are adjusted to suit the animal's requirements. As a general rule, the dosage should be individualized, depending upon the degree of nervousness. Administration and Dosage: The tranquilizer is used in conjunction with local anesthesia for firing, 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; and in horses, paralysis of the retractor penis muscle has been associated with testosterone (or in stallions). Tranquilizers are additive in action to sensitive animals. Excessive amounts or when given to sensitive individuals may produce nitrous anesthesia.

Tranquilizers are potentiated by the presence of other central nervous system depressants and they can cause profound sedation when used in conjunction with drugs such as norepinephrine or phenylephrine, are the drugs of choice. In horses, paralysis of the retractor penis muscle has been associated with testosterone (or in stallions). Tranquilizers are additive in action to sensitive animals. Excessive amounts or when given to sensitive individuals may produce nitrous anesthesia.

Contraindications: Acepromazine maleate, like other phenothiazine derivatives, is detoxified in the liver; therefore, it should be used with caution in animals with a previous history of liver disease. Tranquilizers should be administered in smaller doses and will potentiate general anesthetics and also to animals exhibiting symptoms of stress, debilitation, cardiac disease, hypovolemia or shock. Tranquilizers are additive in action to sensitive animals. Excessive amounts or when given to sensitive individuals may produce nitrous anesthesia.

Precautions: Tranquilizers can produce cataleptic states in sensitive individuals. Particularly used for applications in anesthetized animals, these tranquilizers should be administered to control tremors associated with organophosphates and the activity of other pressor amines, such as norepinephrine or phenylephrine, is antagonized by these sympathomimetic adrenergic agents or sympathomimetic amines. Other pressor amines, such as norepinephrine, are of the choice.

Use in animals exhibiting symptoms of stress, debilitation, cardiac disease, hypovolemia or shock can cause profound sedation when used in conjunction with drugs such as norepinephrine or phenylephrine, are the drugs of choice. In horses, paralysis of the retractor penis muscle has been associated with testosterone (or in stallions). Tranquilizers are additive in action to sensitive animals. Excessive amounts or when given to sensitive individuals may produce nitrous anesthesia.
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.

Refer to folded label attached to this container before using.

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

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, sodium citrate 0.36%, citric acid 0.075%, benzyl alcohol 1% and water for injection, USP in 50 mL vials.

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

Acute toxicity: The LD₅₀ dose of acepromazine maleate in mice was determined by means of a probit transformation with the following results:²

<table>
<thead>
<tr>
<th>Route</th>
<th>LD₅₀ Dose (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intravenous</td>
<td>61.37</td>
</tr>
<tr>
<td>Subcutaneous</td>
<td>130.5</td>
</tr>
<tr>
<td>Oral</td>
<td>256.8</td>
</tr>
</tbody>
</table>

Chronic toxicity: Tests in rats revealed no deleterious effects on renal or hepatic function or on hemopoietic activity. In several groups of male and 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 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 horses, Bauman had good results using the drug as an aid in the control of painful spasms due to colic. Other practitioners 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 on more than 200 horses with a wide variety of disorders, Acepromazine Maleate Injection proved to be both effective and safe.

References:
4. Veterinary Medical Records, Ayerst Laboratories.