

## Physicians Prescribing Information

### **PROMACE VETERINARY**

#### **Solution for Injection ; For Veterinary Use Only**

**NAME OF PRODUCT:** PROMACE VETERINARY

**DESCRIPTION:** 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 affect are added advantages. According to Baker 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 formula:  $C_{23}H_{26}N_2O_5S$

**ACTIONS:** PromAce Veterinary 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 Veterinary 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 Veterinary 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 Veterinary 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.

**CONTRAINDICATIONS:** Phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride. Therefore, do not use PromAce Veterinary (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 Veterinary, 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 Veterinary. This risk should be duly considered prior to the administration of PromAce Veterinary 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 Veterinary (Acepromazine Maleate Injection, USP) May be given intravenously, intramuscularly or subcutaneous. 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 = 0.55-1.10 mg/kg of body weight.

Cats: 0.5-1 mg/lb of body weight = 1.10-2.21 mg/kg of body weight.

Horses: 2-4 mg/100 lb of body weight = 4.41-8.82 mg/100 kg 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.

[ Comparison tablets: 1 lb = 0.454 kg ; 1 kg = 2.205 lb ]

**HOW SUPPLIED:** Each mL contains 10 mg 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. Stored at controlled room temperature, in a cool place, below 25° C.

**TOXICOLOGY:** Acute and chronic toxicity have shown a very low order of toxicity.

**Acute toxicity:** The LD50 dose of PromAce Veterinary in mice was determined by means of a probit transformation with the following results: Intravenous route - 61.37 mg/kg ; Subcutaneous route - 130.5 mg/kg ; Oral route - 256.8 mg/kg

**Chronic Toxicity:** Tests in rats revealed no deleterious effects on renal or hepatic function or on hemopoetic 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 Veterinary (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 in dogs, cats and horses given PromAce Veterinary injectable 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 quite and not in an excited state. In a trial on more than 200 horses with a wide variety of disorders, PromAce Veterinary Injectalbe proved to be both effective and safe.

**ISRAELI DRUG REGISTRATION NUMBER:** 080-59-92164-00

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Date of (partial) revision of text: 13.2.2003

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