

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ACP Injection 10 mg/ml Solution for Injection.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	<u>% w/v</u>
<b>Active substance:</b>	
Acepromazine	1.0
(as acepromazine maleate	1.355)

#### **Excipients:**

Phenol (preservative)	0.3
-----------------------	-----

For a full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Solution for injection.  
Pale yellow solution.

### 4. CLINICAL PARTICULARS

#### 4.1 Target species

Horses.

#### 4.2 Indications for use, specifying the target species

*Anaesthetic Premedication:* Following acepromazine administration, the amount of anaesthetic necessary to induce anaesthesia is considerably reduced. This reduction is approximately one-third of a suitable induction agent.

*Tranquillisation:* Acepromazine tranquillisation (ataraxy) involves a modification of temperament which is not associated with hypnosis, narcosis or marked sedation. This is achieved with low doses of acepromazine. At low doses, acepromazine reduces anxiety which is beneficial for use in horses prior to shoeing or transportation.

*Sedation:* At higher dose rates acepromazine is an effective sedative, as an adjunct to, or replacement for, physical restraint e.g. dentistry, handling and shoeing. The relaxant effects aid examination of the penis in horses and the treatment of tetanus and choke.

### **4.3 Contraindications**

Do not administer to breeding stallions. Paralysis of the retractor penis muscle has been associated with the use of parenterally administered acepromazine in horses.

Do not use this product in conjunction with organophosphates and/or procaine hydrochloride, as it may enhance activity and potential toxicity.

Do not, in any circumstances, ride horses within the 36 hours following administration of the product.

See section 4.7

### **4.4 Special warnings for each target species**

Duration of action may be prolonged and this should be remembered when riding, as acepromazine may affect performance and appear in drug tests for some time.

Acepromazine has little, if any, analgesic effect so that painful procedures must be avoided, particularly where animals are known to have unpredictable temperaments. Therefore, the usual precautions should be maintained when handling sedated horses.

During sedation, horses will normally retain visual and auditory acuity, so that loud sounds and rapid movements may cause arousal from the sedated state. It is therefore important to keep treated horses in a quiet environment and avoid sensory stimulation as far as possible.

Take adequate precautions to maintain sterility.

Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, discard the product.

### **4.5 Special precautions for use**

#### **i. Special precautions for use in animals**

Situations may arise where general anaesthesia is required in the 4 - 6 hours following use of the product. In such cases care should be taken to reduce the induction dose of other premedicants and anaesthetic agents, particularly parenteral barbiturates, so as to avoid potentiation and additive depressant effects.

When administered to male horses (geldings or stallions), use the lowest dose recommended to produce the required effect.

Acepromazine is an adrenoceptor blocking drug and this causes hypotension and lowered p.c.v. The product should therefore be administered with great caution, and at low dose rates only to debilitated horses and animals in states of

hypovolaemia, anaemia and shock, or with cardiovascular disease. Rehydration should precede acepromazine administration.

**ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Care should be taken when handling and administering this product to avoid exposure.

Take precautions to avoid accidental injection or self-administration of this potent drug. In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician. Symptomatic treatment may be required.

Avoid contact with the eyes. If accidental eye contamination occurs, flushed gently with fresh running water for 15 minutes and seek medical advice should be sought if irritation persists.

In the event of accidental skin contamination, contaminated clothing should be removed and the area washed with large amounts of soap and water. Medical advice should be sought if irritation persists.

Wash hands and exposed skin thoroughly after use.

**4.6 Adverse reactions (frequency and seriousness)**

Acepromazine has caused paraphimosis, sometimes as a sequel to priapism. When extrusion of the penis occurs, the owner should be advised to inform his veterinary surgeon if retraction of the penis does not take place within 2 - 3 hours. Suitable treatments have been described in the veterinary literature e.g. manual compression during the period of general anaesthesia, penile support and manual compression, use of an Esmarch bandage, or drug reversal (e.g. slow intravenous administration of benztropine mesylate).

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

**4.7 Use during pregnancy, lactation or lay**

Do not administer to pregnant mares.

**4.8 Interaction with other medicinal products and other forms of interaction**

Tranquilisers are additive to the actions of other depressants and will potentiate general anaesthesia (see section 4.2, indications for use).

**4.9 Amounts to be administered and administration route**

By intramuscular injection: 0.03 - 0.10 mg per kg bodyweight. Approximately equivalent to 0.15 - 0.5 ml of 10 mg/ml injection per 50 kg (approx. 1 cwt) bodyweight.

By intravenous injection: As for intramuscular, except that it is recommended the injection is made slowly.

Normally, single doses of acepromazine are administered. Long term use is not recommended. On the rare occasions that repeat dosing is required, the dosing interval should be 36 - 48 hours.

Take adequate precautions to maintain sterility. Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, discard the product.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

Transient dose-dependent hypotension may occur in cases of accidental overdose. Therapy should consist of discontinuing any other hypotensive treatment, supportive care such as intravenous infusion of warm isotonic saline to correct hypotension and close monitoring. In severe cases treatment with norepinephrine may be indicated but its use must be based on a careful evaluation of the benefit risk balance by the responsible veterinary surgeon.

Epinephrine (adrenaline) is contra-indicated in the treatment of acute hypotension produced by overdosage of acepromazine maleate, since further depression of systemic blood pressure can result.

#### **4.11 Withdrawal period(s)**

Not authorised for use in horses intended for human consumption.

### **5. Pharmacological properties**

Pharmacotherapeutic group: Antipsychotics

ATCvet code: QN05AA04

#### **5.1. Pharmacodynamic properties**

Acepromazine is a phenothiazine. It is a central nervous system depressant with associated activity on the autonomic system. Phenothiazines have a central action due to inhibition of dopamine pathways, resulting in alteration of mood, reduction in fear and removal of learned or conditioned responses.

Acepromazine possesses anti-emetic, hypothermic, hypotensive and anti-spasmodic properties and shows a marked potentiating effect on barbiturate anaesthesia.

#### **5.2 Pharmacokinetic particulars**

The length of action of acepromazine appears to be prolonged and to be dose dependent.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Phenol  
Sodium hydroxide or  
Maleic acid (for pH adjustment)  
Water for injections

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.  
Shelf life after opening of the immediate packaging: 28 days.

### **6.4 Special precautions for storage**

Do not store above 25°C. Protect from light. Following withdrawal of the first dose, use remainder of the product within 28 days. Discard unused material.

### **6.5 Nature and composition of immediate packaging**

20 ml clear glass (Type II) vial, closed with a grey chlorobutyl rubber bung and aluminium crimped seal.

### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Any unused veterinary medicinal product or waste material derived from the use of such veterinary medicinal products should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

Elanco Europe Ltd  
Lilly House  
Priestley Road  
Basingstoke  
Hampshire  
RG24 9NL

## **8. MARKETING AUTHORISATION NUMBER**

Vm 00879/4013

**9. DATE OF FIRST AUTHORISATION**

30 June 1992

**10. DATE OF REVISION OF THE TEXT**

January 2016

Approved: 13 January 2016

A handwritten signature in black ink, consisting of a large, stylized capital letter 'R' with a loop at the top and a horizontal stroke at the bottom.