# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AceSedate 10 mg/ml solution for injection for horses

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:

| | |
|---|---|
| Acepromazine | 10 mg |
| (as acepromazine maleate | 13.55 mg |

Excipients:

| | |
|---|---|
| Phenol (preservative) | 3.0 mg |

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for injection.
Clear 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.

Tranquilisation: Acepromazine tranquilisation (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

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product contains a potent sedative; care should be taken when handling and administering this product to avoid accidental self-exposure. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician but DO NOT DRIVE as sedation may occur. Symptomatic treatment may be required.

This product may cause irritation of skin and eyes. Avoid contact with skin and eyes. If accidental eye contact occurs, flush gently with fresh running water for 15 minutes and seek medical advice if any irritation persists. In the event of accidental skin contact, wash the contaminated area 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.

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. The closure may be safely punctured up to 38 times.

## 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 (for pH adjustment)
Maleic acid (for pH adjustment)
Water for injections

### 6.2 Major incompatibilities

None known.

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after opening of the immediate packaging: 28 days.

### 6.4 Special precautions for storage

Do not store above 25°C.
Following withdrawal of the first dose, use remainder of the product within 28 days.

Discard unused material.
Keep the vial in the outer carton in order to protect from light.
Do not freeze.

### 6.5 Nature and composition of immediate packaging

20 ml amber glass (Type I) vial or 50 ml amber glass (Type II) vial, closed with a grey chlorobutyl rubber bung and aluminium crimped seal with plastic flip-cap.

Not all pack sizes may be marketed.

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

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

## 7. MARKETING AUTHORISATION HOLDER

Jurox (UK) Limited
Second Floor, Richmond House
105 High Street, Crawley
West Sussex RH10 1DD
United Kingdom

## 8. MARKETING AUTHORISATION NUMBER

Vm 25296/4008

## 9. DATE OF FIRST AUTHORISATION

21 February 2019

## 10. DATE OF REVISION OF THE TEXT

February 2019

**PROHIBITION OF SALE, SUPPLY AND/OR USE**
To be supplied only on veterinary prescription.

Approved: 21 February 2019