SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AceSedate 2 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Acepromazine 2.0 mg
(as acepromazine maleate 2.71 mg)

Excipients:
Phenol 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

Dogs and cats

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.

Sedation: At higher dose rates acepromazine is a sedative.

4.3 Contraindications

Do not use in pregnant animals.
Do not use on a long term basis in individual animals.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i) Special precautions for use in animals

Acepromazine is hypotensive. Particular care should therefore be taken in hypovolaemic animals; rehydration should precede acepromazine administration.

In some dogs, particularly Boxers and other short-nosed breeds, spontaneous fainting or syncope may occur due to sinoatrial block caused by excessive vagal tone. An attack may be precipitated by an injection of acepromazine, so a low dose should be used. Where there is a history of this type of syncope, or if it is suspected because of excessive sinus arrhythmia, it may be advantageous to control the dysrhythmia with atropine given just before the acepromazine.

Large breeds: It has been noted that large breeds of dog are particularly sensitive to acepromazine and the minimum dose possible should be used in these breeds.

ii) 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)

Cardiac dysrhythmia may follow rapid intravenous injection. See also section 4.5 (i), Special precautions for use in animals.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy

4.8 Interaction with other medicinal products and other forms of interaction

Acepromazine is 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

Premedication: 0.03 - 0.125 mg per kg bodyweight by intramuscular, subcutaneous or slow intravenous injection.

Other uses: By intramuscular or subcutaneous injection 0.0625 - 0.125 mg per kg bodyweight. Approximately equivalent to 0.625 - 1.25 ml of 2 mg/ml injection per 20 kg bodyweight. By intravenous injection - as for intramuscular, except that it is recommended the injection is made slowly.

The maximum dose that should be given is 4 mg acepromazine per animal.
Normally single doses of acepromazine are administered (see section 4.3, Contraindications).

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.

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 applicable.

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

This veterinary medicinal product can be mixed in the same syringe with aqueous solutions for injection containing buprenorphine as hydrochloride, methadone as hydrochloride, butorphanol as tartrate, and medetomidine and dexmedetomidine as hydrochlorides. Syringes with these mixtures should be used as soon as practicable. Any unused mixed solution remaining in the syringe should be disposed appropriately.
In the absence of further compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after opening of the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
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, closed with a chlorobutyl rubber bung and aluminium crimped seal in a cardboard box.

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 such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4219

9. DATE OF FIRST AUTHORISATION

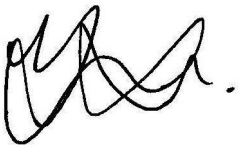
11 June 2018

10. DATE OF REVISION OF THE TEXT

August 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.



Approved: 14 August 2023