SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ACP Tablets 10 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: mg/tablet

Acepromazine	10.0
(as Acepromazine maleate	13.54)

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
Pale yellow biconvex tablet, approximately 6.5 mm in diameter, scored on one side only.

4. CLINICAL PARTICULARS

4.1 Target species

Dog and cat.

4.2 Indications for use, specifying the target species

Anaesthetic premedication: Following acepromazine administration, the amount of anaesthetic dose 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.

Sedation: At higher dose rates acepromazine is a sedative.

Travel Sickness: A dose of 1 mg per kg given orally a quarter to half an hour before a light meal is effective in the prevention of travel sickness. Idiopathic vomiting may be controlled by acepromazine.

4.3 Contraindications

Do not use in pregnant animals (see section 4.7).
Do not use on a long term basis in individual animals.

4.4 Special warnings for each target species

There are no known special warnings.

4.5 Special precautions for use

i) Special precautions for use in animals

Acepromazine is hypotensive. Particular care should therefore be taken in hypovolaemic subjects; 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, and an attack may be precipitated by 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

In the event of accidental ingestion seek medical advice, showing the package leaflet to the physician.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

See section 4.5 (i), Special precautions for use in animals.

4.7 Use during pregnancy, lactation or lay

No formal studies on the safety of ACP Tablets in pregnant animals have been conducted (see section 4.3, Contraindications).

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

0.25 - 3 mg per kg bodyweight by oral administration. Onset of effects will be observed after 10 - 15 minutes.

Normally single doses of acepromazine are administered (see section 4.3, Contraindications).

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, anti-convulsant, 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

Lactose monohydrate
Maize starch
Pregelatinised starch
Povidone K29-32
Magnesium stearate

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of veterinary medicinal product as packaged for sale: 4 years.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

White opaque polypropylene tub with a white opaque low density polyethylene lid, containing 500 tablets.

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

Elanco Europe Ltd
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Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4011

9. DATE OF FIRST AUTHORISATION

24 July 1992

10. DATE OF REVISION OF THE TEXT

September 2020

Approved 25 September 2020