PACKAGE LEAFLET: ACP Tablets 10 mg

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, UK.
Tel: 01256 353131
Manufacturer responsible for batch release:
Surepharm Services Ltd., Bretby Business Park Bretby, Burton Upon Trent, DE15 0YZ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT ACP Tablets 10 mg

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

10 mg Acepromazine (as acepromazine maleate 13.54 mg). Tablets are pale yellow in colour.

4. INDICATION(S)

The tablets are intended for use only in cats and dogs.

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.

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

7. TARGET SPECIES

Dog and cat.
For animal treatment only.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Special precautions: 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, and an attack may be precipitated by acepromazine. 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.

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.

Pregnancy:
Do not use in pregnant animals.

Overdose (symptoms, emergency procedures, antidotes):
Overdosage:
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

POM-V To be supplied only on veterinary prescription.
Vm 00879/4011
Containers of 500 x 10 mg tablets.