ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

NATURE/TYPE: Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ACP Injection 2 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Contains: 0.2% w/v Acepromazine
(as acepromazine maleate 0.271% w/v), and 0.3% w/v phenol as preservative.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Dosage: Dogs and cats: 0.03 - 0.125 mg/kg bodyweight. By intramuscular, subcutaneous or slow intravenous injection.

8. WITHDRAWAL PERIOD(S)

Not Applicable

9. SPECIAL WARNING(S), IF NECESSARY

For full details of uses, contra-indications, user warnings and other warnings, see package leaflet.
Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, discard the product.

10. EXPIRY DATE

EXP:
Following withdrawal of the first dose, use remainder of the product within 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.
Keep the vial in outer container.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, UK.
Tel: 01256 353131

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4012

POM-V

17. MANUFACTURER'S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

NATURE/TYPE: Glass Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ACP Injection 2 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Contains: 0.2% w/v Acepromazine (as acepromazine maleate 0.271% w/v), and 0.3% w/v phenol as preservative.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Dosage: Dogs and cats: 0.03 - 0.125 mg/kg bodyweight. By intramuscular, subcutaneous or slow intravenous injection.

8. WITHDRAWAL PERIOD(S)

Not Applicable

9. SPECIAL WARNING(S), IF NECESSARY

For full details of uses, contra-indications, user warnings and other warnings, see package leaflet.
Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, discard the product.

10. EXPIRY DATE

Used by end:
Once broached, use by:
Following withdrawal of the first dose, use remainder of the product within 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.
Keep the vial in outer container.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

For advice on disposal of unused product or empty containers, see package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, UK.
Tel: 01256 353131

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4012

POM-V

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
ACP Injection 2 mg/ml Solution for Injection

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:
Bela-Pharm GmbH & Co. KG Lohner Straße 19
49377 Vechta
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ACP Injection 2 mg/ml Solution for Injection

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

ACP Injection 2mg/ml is a pale yellow solution, which contains 0.2% w/v Acepromazine (as acepromazine maleate 0.271% w/v), and 0.3% w/v phenol as preservative.

4. INDICATION(S)

The 2 mg/ml solution is 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.
Acepromazine possesses anti-emetic, 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

Cardiac dysrhythmia may follow rapid intravenous injection.

7. TARGET SPECIES

Cats and dogs

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

Take adequate precautions to maintain sterility.
Normally single doses of acepromazine are administered.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.
Do not store above 25°C.
Protect from light.
Following withdrawal of the first dose, use the remainder of the product within 28 days. When the container is broached for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded, should be worked out. This discard date should be written in the space provided on the label.
Keep the vial in outer container.
Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, discard the product.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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.

Special precautions for use in animals:
Acepromazine is hypotensive. Particular care should therefore be taken in hypovolaemic animals; rehydration should precede acepromazine administration.

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 leaflet or the label to the physician.
Symptomatic treatment may be required.
Avoid contact with 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.

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 over-dosage 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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

For Animal Treatment Only
Subcutaneous injection is non irritant and efficacious, especially in cats.
20 ml glass vials.
Vm 00879/4012
To be supplied only on veterinary prescription.

POM-V

Approved 25 September 2020