ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Acecare 2 mg/ml Solution for Injection for Dogs and Cats
Acepromazine (as acepromazine maleate)

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of solution contains

Active substance:

Acepromazine	2 mg
(as acepromazine maleate	2.71 mg)

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

0.03 - 0.125 mg per kg bodyweight by intramuscular, subcutaneous or slow intravenous injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf life after first opening of the immediate packaging: 28 days.
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Keep the vial in the outer carton in order to protect from light. Following withdrawal of the first dose, use remainder of the product within 28 days.
Discard unused material.

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

Dispose of waste material in accordance with local requirements.

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 the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4018

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml Vial Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Acecare 2 mg/ml Solution for Injection for Dogs and Cats
Acepromazine (as acepromazine maleate)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Acepromazine (as acepromazine maleate) 2 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular, subcutaneous or slow intravenous Injection.

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP
Once broached, use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Acecare 2 mg/ml Solution for Injection for Dogs and Cats

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

Marketing authorisation holder:
Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Acecare 2 mg/ml Solution for Injection for Dogs and Cats
Acepromazine (as acepromazine maleate)

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

Each ml of pale yellow solution contains:

Active substance:

Acepromazine	2 mg
(as acepromazine maleate	2.71 mg)

Excipients:

Phenol (as preservative)	3 mg

4. INDICATION(S)

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.

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 (see section 12).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and Cats.

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 bodweight. 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 5, Contraindications).

9. ADVICE ON CORRECT ADMINISTRATION

Take adequate precautions to maintain sterility. Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, discard the product.

Do not exceed 40 broachings per vial.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Do not store above 25^{o}C. Keep the vial in the outer carton in order to protect from light. Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after “EXP”. The expiry date refers to the last day of that month.
Shelf life after first opening of the vial: 28 days.

When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

Special precautions for use in animals:

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

Acepromazine may cause hypothermia due to depression of the thermoregulatory centre and peripheral vasodilation.

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 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.

This product contains a potent sedative. Take precautions to avoid accidental injection. 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.

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 and lactation:

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

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). Do not use this product in conjunction with organophosphates and/or procaine hydrochloride, as it may enhance activity and potential toxicity.

Overdose (symptoms, emergency procedures, antidotes):

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.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

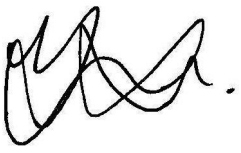
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

20 ml clear glass vials.
Not all pack sizes may be marketed.



Approved: 11 August 2022