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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of solution contains:

Active substance:

Acepromazine	2 mg
(as acepromazine maleate	2.71 mg)

3. PACKAGE SIZE

20 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

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

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening of the immediate packaging: 28 days.
Once opened use by…

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 ºC.
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.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar
An Animalcare Company

14. MARKETING AUTHORISATION NUMBER

Vm 32742/4018

15. 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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Acepromazine (as acepromazine maleate) 2 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by…

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Acecare 2 mg/ml Solution for Injection for Dogs and Cats

2. Composition

Each ml of solution contains:

Active substance:
Acepromazine 2 mg
(as acepromazine maleate 2.71 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol	3 mg

Pale yellow solution for injection.

3. Target species

Dogs and cats.

4. Indications for use

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. Special warnings

Special precautions for safe use in the target species:

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 dogs 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.

Special precautions for the protection of the environment:

Not applicable.

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

Overdose:

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.

Major incompatibilities:

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

7. Adverse events

Dogs and cats:

Undetermined frequency (cannot be estimated from the available data):	Arrhythmia*

* after rapid intravenous injection

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
E-mail: adverse.events@vmd.gov.uk
Website:https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes and method of administration

Intramuscular, subcutaneous or slow intravenous injection.

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 '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 periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25°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 precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with

any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

20 ml clear glass vials. Cardboard box containing 1 vial of 20 ml.
Not all pack sizes may be marketed.

15.PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

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

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Gavin Hall
Approved: 16 April 2025