ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

20 ml printed carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AceSedate 2 mg/ml solution for injection for dogs and cats
Acepromazine

2. STATEMENT OF ACTIVE SUBSTANCES

Acepromazine 2.0 mg/ml (as acepromazine maleate 2.71 mg/ml)
Preservative: Phenol

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.
Administration: Dogs and cats – intramuscular, subcutaneous or slow intravenous injection

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first broaching vial: 28 days
Once broached, use by …….

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Keep the vial in the outer carton in order to protect from light.
Do not freeze.

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. **POM-V**

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4219

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AceSedate 2 mg/ml solution for injection for dogs and cats
Acepromazine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

2 mg/ml

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

20 ml

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Administration: Dogs and cats – intramuscular, subcutaneous or slow intravenous injection

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP {month/year}
Shelf life after first broaching vial: 28 days
Once broached, use by_____

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only. **POM-V**

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
AceSedate 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
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturers responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Lovain-La-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AceSedate 2 mg/ml solution for injection for dogs and cats.
Acepromazine

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

Acepromazine 2.0 mg/ml (as acepromazine maleate 2.71 mg/ml)
with phenol 3.0 mg/ml as antimicrobial preservative

Clear yellow solution

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.

If you notice any serious effects or other effects not mentioned in this package leaflet, 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 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.

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.

10. WITHDRAWAL PERIOD

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25ºC.
Keep the vial in the outer carton in order to protect from light.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
Shelf life after opening the container: 28 days.

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.

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:
This product contains a potent sedative; care should be taken when handling and administering this product to avoid accidental self-exposure. 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.

This product may cause irritation of skin and eyes. Avoid contact with skin and 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:
The safety of AceSedate Injection 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.

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.

Slow intravenous injection of norepinephrine (noradrenaline) should be used whenever a hypertensive agent is required to reverse any fall in blood pressure.

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:
This veterinary medicinal product can be mixed in the same syringe with aqueous solutions for injection containing buprenorphine as hydrochloride, methadone as hydrochloride, butorphanol as tartrate, and medetomidine and dexmedetomidine as hydrochlorides. Syringes with these mixtures should be used as soon as practicable. Any unused mixed solution remaining in the syringe should be disposed appropriately.
In the absence of further 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 material 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

August 2023

15. OTHER INFORMATION

20 ml vial

For any information about this veterinary medicinal product, please contact the Zoetis UK Limited

POM-V To be supplied only on veterinary prescription.

Approved 24 August 2023