ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

20 ml printed carton
50 ml printed carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AceSedate 10 mg/ml solution for injection for horses
Acepromazine

2. STATEMENT OF ACTIVE SUBSTANCES

Acepromazine 10.0 mg/ml (as acepromazine maleate 13.55 mg/ml)
Preservative: Phenol

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml
50 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Administration: Horses – intramuscular and intravenous injection.

8. WITHDRAWAL PERIOD (S)

Not authorised for use in horses intended for human consumption.

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

12. SPECIFIC 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 42058/4222

17. MANUFACTURER'S BATCH NUMBER

See base for Batch ad EXP

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
20 ml vial label
50 ml vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AceSedate 10 mg/ml solution for injection for horses
Acepromazine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

10 mg/ml

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

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Administration: horses – intramuscular or intravenous injection.

5. WITHDRAWAL PERIOD(S)

Not authorised for use in horses intended for human consumption.

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.

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B. PACKAGE LEAFLET

PACKAGE LEAFLET:
AceSedate 10 mg/ml solution for injection for horses.

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 10 mg/ml solution for injection for horses.
Acepromazine

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

Acepromazine 10.0 mg/ml (as acepromazine maleate 13.55 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. At low doses, acepromazine reduces anxiety which is beneficial for use in horses prior to shoeing or transportation.

Sedation: At higher dose rates acepromazine is an effective sedative, as an adjunct to, or replacement for, physical restraint e.g. dentistry, handling and shoeing. The relaxant effects aid examination of the penis in horses and the treatment of tetanus and choke.

5. CONTRAINDICATIONS

Do not administer to breeding stallions. Paralysis of the retractor penis muscle has been associated with the use of parenterally administered acepromazine in horses.

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

Do not, in any circumstances, ride horses within the 36 hours following administration of the product.
See Special Warnings – Pregnancy.

6. ADVERSE REACTIONS

Acepromazine has caused paraphimosis, sometimes as a sequel to priapism. When extrusion of the penis occurs, the owner should be advised to inform his veterinary surgeon if retraction of the penis does not take place within 2 - 3 hours. Suitable treatments have been described in the veterinary literature e.g. manual compression during the period of general anaesthesia, penile support and manual compression, use of an Esmarch bandage.

Accidental intracarotid injection in horses can produce clinical signs ranging from disorientation to convulsive seizures and death.

7. TARGET SPECIES

Horses.

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

By intramuscular injection: 0.03 - 0.10 mg per kg bodyweight. Approximately equivalent to 0.15 - 0.5 ml of 10 mg/ml injection per 50 kg (approx. 1 cwt) bodyweight.

By intravenous injection: As for intramuscular, except that it is recommended the injection is made slowly.

Normally, single doses of acepromazine are administered. Long term use is not recommended. On the rare occasions that repeat dosing is required, the dosing interval should be 36 - 48 hours.
The closure may be safely punctured up to 38 times with careful broaching.

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(S)

Not authorised for use in horses intended for human consumption.

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 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 the month.
Following withdrawal of the first dose, use remainder of the product within 28 days
Discard unused material.
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 container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Duration of action may be prolonged and this should be remembered when riding, as acepromazine may affect performance and appear in drug tests for some time.

Acepromazine has little, if any, analgesic effect so that painful procedures must be avoided, particularly where animals are known to have unpredictable temperaments. Therefore, the usual precautions should be maintained when handling sedated horses.

During sedation, horses will normally retain visual and auditory acuity, so that loud sounds and rapid movements may cause arousal from the sedated state. It is therefore important to keep treated horses in a quiet environment and avoid sensory stimulation as far as possible.

Special precautions for use in animals:
Situations may arise where general anaesthesia is required in the 4 - 6 hours following use of the product. In such cases care should be taken to reduce the induction dose of other premedicants and anaesthetic agents, particularly parenteral barbiturates, so as to avoid potentiation and additive depressant effects.

When administered to male horses (geldings or stallions), use the lowest dose recommended to produce the required effect.

Acepromazine is an adrenoceptor blocking drug and this causes hypotension and lowered p.c.v. The product should therefore be administered with great caution, and at low dose rates only to debilitated horses and animals in states of hypovolaemia, anaemia and shock, or with cardiovascular disease. Rehydration should precede acepromazine administration.

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:
Do not administer to pregnant mares.

Interaction with other medicinal products and other forms of interaction:
Tranquilisers are additive to the actions of other depressants and will potentiate general anaesthesia (see Indications).

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. In severe cases treatment with norepinephrine may be indicated but its use must be based on a careful evaluation of the benefit risk balance by the responsible veterinary surgeon.

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:
None known.

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 2023

<15. OTHER INFORMATION>

20 ml vial
50 ml vial
Not all pack sizes may be marketed.
For any information about this veterinary medicine product, please contact Zoetis UK Limited

For animal treatment only.

POM-V To be supplied only on veterinary prescription.

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Approved 24 August 2023