ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Outer carton
Glass vials of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Temprace 0.5 mg/ml solution for injection for dogs and cats
acepromazine

2. STATEMENT OF ACTIVE SUBSTANCES

Acepromazine 0.5 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
20 ml
100 ml

5. TARGET SPECIES

Dogs, cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the container: 28 days
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

Disposal: read package leaflet

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

For animal treatment only.
Supply / use: (National issue)

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

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41821/4053

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vials of 10 or 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Temprace 0.5 mg/ml solution for injection for dogs and cats
Acepromazine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

0.5 mg/ml

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

10 ml
20 ml

4. ROUTE(S) OF ADMINISTRATION

IV only

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 28 days
Once broached use by ……..

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Temprace 0.5 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:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Temprace 0.5 mg/ml solution for injection for dogs and cats
acepromazine

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

Each ml contains:
Active substance:
Acepromazine 0.5 mg
(equivalent to 0.678 mg acepromazine maleate)

Excipients:
Phenol 1.67 mg

Clear yellow to orange solution.

4. INDICATION(S)

For anaesthetic premedication, tranquilisation and sedation.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in pregnant animals.
Do not use on a long term basis in individual animals.
See also section on Special Warnings (Interactions).

6. ADVERSE REACTIONS

Cardiac dysrhythmia (abnormal heart rhythm) may follow rapid intravenous injection. See also section on Special Warnings (Special precautions for use in animals).
If you notice any side effects, even those not already listed in this package leaflet or if 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

For intravenous injection only. It is recommended that the injection is made slowly.

Premedication: 0.03−0.125 mg acepromazine per kg bodyweight, corresponding to 0.6−2.5 ml product per 10 kg bodyweight

Other uses: 0.0625−0.125 mg acepromazine per kg bodyweight, corresponding to 1.25−2.5 ml product per 10 kg bodyweight.

The maximum dose that should be given is 4 mg acepromazine per animal.
Normally single doses of acepromazine are administered (see section Special precautions for use in animals). Following acepromazine administration, the amount of anaesthetic necessary to induce anaesthesia may be considerably reduced.

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.
The maximum number of vial punctures when using needle sizes of 21G and 23G should not exceed 100 and when using a 18G needle, the maximum should not exceed 40.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
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 after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 28 days

12. SPECIAL WARNING(S)

Special warnings for each target species:
Since the individual response to acepromazine may be variable, reliable sedation may not be achieved in some animals. In these individuals, other drugs or drug combinations should be considered.

In the absence of suitable studies regarding efficacy, the product should not be administered via the subcutaneous or intramuscular routes.

Special precautions for use in animals:
For the veterinarian:
Acepromazine is hypotensive (lowers the blood pressure) and can cause a transient reduction in haematocrit. The product should therefore be administered with great caution, and at low dose rates only, to animals in states of hypovolaemia, anaemia and shock or with cardiovascular disease. Rehydration should precede acepromazine administration.
Acepromazine may cause hypothermia due to depression on the thermoregulatory centre and peripheral vasodilation.
Acepromazine has negligible analgesic effects. Painful activities should be avoided when handling tranquillized animals.
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.
In dogs with the ABCB1-1Δ (also called MDR1) mutation, acepromazine tends to cause more profound and prolonged sedation. In these dogs the dose should be reduced by 25%-50%.
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 the 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.
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, contaminated clothing should be removed and the area washed 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:
Do not use in pregnant animals. The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

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.

Interactions:
For the veterinarian:
Acepromazine is additive to the actions of other CNS depressants and will potentiate general anaesthesia (see section Dosage for each species, route(s) and method of administration).
Do not use this product in conjunction with organophosphates and/or procaine hydrochloride, as it may enhance activity and potential toxicity.

Incompatibilities:
For the veterinarian:
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

Any unused veterinary medicinal product or waste materials 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

DD-MM-YYYY

15. OTHER INFORMATION

Pack sizes:
10 ml, 20 ml or 100 ml.
Not all pack sizes may be marketed.

Approved 09 April 2018