[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Temprace 0.5 mg/ml solution for injection for dogs and cats (AT, BE, BG, CY, CZ, EL, ES, FR, HR, HU, IE, IT, LU, NL, PT, RO, SI, SK, UK (NI))
Temprace Vet 0.5 mg/ml solution for injection for dogs and cats (DK, EE, FI, IS, LT, LV, PL, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol	1.67 mg
Sodium chloride	
Sodium hydroxide (for pH adjustment)	
Maleic acid (for pH adjustment)	
Water for injections	

Clear yellow to orange solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats.

3.2 Indications for use for each target species

For anaesthetic premedication, tranquilisation and sedation.

3.3 Contraindications

Do not use in pregnant animals.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use on a long term basis in individual animals.
See also section 3.8.

3.4 Special warnings

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 veterinary medicinal product should not be administered via the subcutaneous or intramuscular routes.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Acepromazine is hypotensive and can cause a transient reduction in haematocrit. The veterinary medicinal 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 of 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 veterinary medicinal product contains a potent sedative, care should be taken, when handling and administering the veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs, cats:

Undetermined frequency (cannot be estimated from the available data)	Arrhythmia[a]

[a] Following rapid intravenous injection. See also section 3.5 (Special precautions for safe use in the target species).

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

Pregnancy:
Do not use (during the whole or part of the pregnancy).

3.8 Interaction with other medicinal products and other forms of interaction

Acepromazine is additive to the actions of other CNS depressants and will potentiate general anaesthesia (see section 3.9).
Do not use this veterinary medicinal product in conjunction with organophosphates and/or procaine hydrochloride, as it may enhance activity and potential toxicity.

3.9 Administration routes and dosage

Intravenous use. It is recommended that the injection is made slowly.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Premedication: 0.03−0.125 mg acepromazine per kg bodyweight, corresponding to 0.6−2.5 ml veterinary medicinal product per 10 kg bodyweight
Other uses: 0.0625−0.125 mg acepromazine per kg bodyweight, corresponding to 1.25−2.5 ml veterinary medicinal 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 3.5, Special precautions for safe use in the target species). Following acepromazine administration, the amount of anaesthetic necessary to induce anaesthesia may be considerably reduced.

Take adequate precautions to maintain sterility. Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, discard the veterinary medicinal product.
The maximum number of vial punctures when using needle sizes 21G and 23G should not exceed 100 and when using a 18G needle, the maximum should not exceed 40.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QN05AA04

4.2 Pharmacodynamics

Acepromazine is a phenothiazine. It is a central nervous system depressant with associated activity on the autonomic system. Phenothiazines have a central action due to inhibition of dopamine pathways, resulting in alteration of mood, reduction in fear and removal of learned or conditioned responses. Acepromazine possesses anti-emetic, hypothermic, vasodilatory (and therefore hypotensive) and anti-spasmodic properties.

4.3 Pharmacokinetics

The length of action of acepromazine appears to be prolonged and to be dose dependent.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Clear type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box.
Pack sizes: 10 ml, 20 ml and 100 ml.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Temprace 0.5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

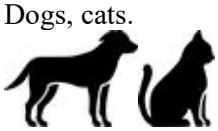
Each ml contains:
Acepromazine 0.5 mg
(equivalent to 0.678 mg acepromazine maleate)

3. PACKAGE SIZE

10 ml
20 ml
100 ml

4. TARGET SPECIES

Dogs, cats.



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within: 28 days.

9. SPECIAL STORAGE PRECAUTIONS

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

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Glass vials of 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Temprace 0.5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. TARGET SPECIES

Dogs, cats.

4. ROUTES OF ADMINISTRATION

Intravenous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. 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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Acepromazine 0.5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

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.

3. Target species

Dogs, cats.

4. Indications for use

For anaesthetic premedication, tranquilisation and sedation.

5. Contraindications

Do not use in pregnant animals.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use on a long term basis in individual animals.
See also section "Special Warnings" (subsection "Interactions with other medicinal products and other forms of interaction").

6. Special warnings

Special warnings:
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 veterinary medicinal product should not be administered via the subcutaneous or intramuscular routes.

Special precautions for safe use in the target species:
Acepromazine is hypotensive (lowers the blood pressure) and can cause a transient reduction in haematocrit. The veterinary medicinal 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 veterinary medicinal product contains a potent sedative, care should be taken, when handling and administering the veterinary medicinal 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 (during the whole or part of the pregnancy). The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:
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 veterinary medicinal 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.

<Special restrictions for use and special conditions for use:>

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, cats:

Undetermined frequency (cannot be estimated from the available data)	Arrhythmia[a]

[a] Following rapid intravenous injection. See also section 'Special precautions for safe use in the target species'.

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: {national system details}.

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

Intravenous use. It is recommended that the injection is made slowly.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

Other uses: 0.0625−0.125 mg acepromazine per kg bodyweight, corresponding to 1.25−2.5 ml veterinary medicinal 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 safe use in the target species). 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 veterinary medicinal 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 periods

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 immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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

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

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:

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

To be completed nationally.