SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

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

Excipients:
Phenol 1.67 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow to orange solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

For anaesthetic premedication, tranquilisation and sedation.

4.3 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 4.8.

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals
Acepromazine is hypotensive 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 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 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.

4.6 Adverse reactions (frequency and seriousness)

Cardiac dysrhythmia may follow rapid intravenous injection. See also section 4.5 (Special precautions for use in animals).

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant animals. The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

4.8 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 4.9).
Do not use this product in conjunction with organophosphates and/or procaine hydrochloride, as it may enhance activity and potential toxicity.

4.9 Amounts to be administered and administration route

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 4.5, Special precautions for use in animals). 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 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antipsychotics
ATCvet code: QN05AA04

5.1. Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium chloride
Sodium hydroxide (for pH adjustment)
Maleic acid (for pH adjustment)
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

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

6.4 Special precautions for storage

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

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

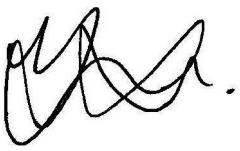
Vm 41821/4053

9. DATE OF FIRST AUTHORISATION

09 April 2018

10. DATE OF REVISION OF THE TEXT

August 2022



Approved: 01 August 2022