

# Temprace 0.5 mg/ml Solution for Injection for Dogs and Cats

Authorised

- Acepromazine maleate

## Product identification

**Medicine name:**

Temprace 0.5 mg/ml Solution for Injection for Dogs and Cats

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**Active substance:**

Acepromazine maleate

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**Target species:**

Dog

Cat

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**Route of administration:**

Intravenous use

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## Product details

**Active substance and strength:**

Acepromazine maleate

0.68 milligram(s) / 1.00 millilitre(s)

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**Pharmaceutical form:**

Solution for injection

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QN05AA04

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Denmark

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**Available in:**

Denmark

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**Package description:**

Clear type I glass vial of 10 ml closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box

Clear type I glass vial of 20 ml closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box

Clear type I glass vial of 100 ml closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Hybrid application (Article 13(3) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Le Vet. Beheer B.V.

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**Marketing authorisation date:**

6/02/2018

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**Manufacturing sites for batch release:**

Produlab Pharma B.V.

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**Responsible authority:**

Danish Medicines Agency

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**Authorisation number:**

58623

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**Date of authorisation status change:**

6/02/2018

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**Reference member state:**

Netherlands

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**Procedure number:**

NL/V/0321/001

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**Concerned member states:**

Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland  
France Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg  
Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden  
United Kingdom (Northern Ireland)

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents