

# Tranquiline 35 mg/ml Oral Gel for Dogs

Authorised

- Acepromazine maleate

## Product identification

**Medicine name:**

Tranquiline 35 mg/ml Oral Gel for Dogs

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**Active substance:**

Acepromazine maleate

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**Target species:**

Dog

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**Route of administration:**

Oral use

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## Product details

**Active substance and strength:**

Acepromazine maleate  
47.50 milligram(s) / 1.00 millilitre(s)

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**Pharmaceutical form:**

Oral gel

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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:**

Italy

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**Package description:**

Prefilled syringe: Container: White, high-density polyethylene syringe barrel. White, low-density polyethylene syringe plunger. Closure: White, high-density polyethylene, push-fit cap. Fill volume: 10 ml Dosing device: The product is presented in an oral dosing syringe which is graduated at 1 ml intervals.

Glass bottle Container: Amber Type III glass bottle of 10 ml volume. Closure: high-density polyethylene/low-density polyethylene child resistant closure Extractable volume 9.8 ml of Tranquiline gel can be withdrawn from each 10 ml amber glass bottle Dosing device: 1.0 ml polypropylene oral dosing syringe, graduated at 0.05 ml intervals, is supplied with the 10 ml amber glass bottle.

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Generic application (Article 13(1) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Floris Holding B.V.

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**Marketing authorisation date:**

2/03/2012

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**Manufacturing sites for batch release:**

Floris Veterinaire Producten B.V.

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**Responsible authority:**

Ministry Of Health

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**Authorisation number:**

105513

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**Date of authorisation status change:**

13/01/2017

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**Reference member state:**

Ireland

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**Procedure number:**

IE/V/0278/001

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**Concerned member states:**

Austria Belgium Bulgaria Cyprus Denmark France Germany Greece Italy  
Netherlands Norway Poland Romania 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

Combined File of all Documents

English (PDF)

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