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Tranquiline 35 mg/ml Oral Gel for Dogs

Authorised

- Acepromazine maleate

Product identification

Medicine name:
Tranquiline 35 mg/ml Oral Gel for Dogs

Active substance:
Acepromazine maleate

Target species:
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Acepromazine maleate
47.50 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Oral gel

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN05AA04

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Norway

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polyethylene/low-density polyethylene child resistant closure Extractable volume 9.8 ml of Tranquiline gel can be withdrawn from each 10 ml amber glass bottle Dosing device: 1.0 ml polypropylene oral dosing syringe, graduated at 0.05 ml intervals, is supplied with the 10 ml amber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

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
Floris Veterinaire Producten B.V.

Marketing authorisation date:
11/04/2023

Manufacturing sites for batch release:
Floris Veterinaire Producten B.V.

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
20-13442

Date of authorisation status change:
11/04/2023

Reference member state:
Ireland

Procedure number:
IE/V/0278/001

Concerned member states:
Austria Belgium Bulgaria Cyprus Denmark France Germany Greece Italy Netherlands Norway Poland Romania Spain Sweden

United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

English (PDF)
Published on: 18/01/2026
Updated on: 14/03/2026
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Package Leaflet

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

Labelling

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

Combined File of all Documents