Source URL: https://medicines.health.europa.eu/veterinary/en/600000050242

Tranquiline 35 mg/ml Oral Gel for Dogs

Authorised

• Acepromazine maleate

Product identification

Medicine name:

Tranquiline 35 mg/ml Oral Gel for Dogs Tranquiline 35 mg/ml πόσιμη γέλη για σκύλους

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

Withdrawal period by route of administration: Oral use:

Dog

Anatomical therapeutic chemical veterinary (ATCvet) codes:

ON05AA04

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Cyprus

Package description:

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polyethylene/low-density polyethylene child resistant closure Extractable volume 9.8 ml of Tranquiline gel can be withdrawn from each 10 ml amber glass bottle Dosing device: 1.0 ml polypropylene oral dosing syringe, graduated at 0.05 ml intervals, is supplied with the 10 ml amber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

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.

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 Holding B.V.

Marketing authorisation date: 18/11/2020
Manufacturing sites for batch release: Floris Veterinaire Producten B.V.
Responsible authority: Veterinary Services, Ministry Of Agriculture, Natural Resources And Environment
Authorisation number: CY00815V
Date of authorisation status change: 18/11/2020
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

Combined File of all Documents

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