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

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN05AA04

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polyethylene/low-density polyethylene child resistant closure Extractable volume 9.8 ml of Tranquiline gel can be withdrawn from each 10 ml amber glass bottle Dosing device: 1.0 ml polypropylene oral dosing syringe, graduated at 0.05 ml intervals, is supplied with the 10 ml amber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

English (PDF)
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