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Tranquigel 35 mg/g oral gel for dogs and horses

Authorised

- Acepromazine maleate

Product identification

Medicine name:
Tranquigel 35 mg/g oral gel for dogs and horses

Active substance:
Acepromazine maleate

Target species:
Dog
Horse

Route of administration:
Oral use

Product details

Active substance and strength:
Acepromazine maleate
47.52 milligram(s) / 1.00 gram(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:
Sweden

Package description:
Cardboard box with 1 white LLDPE (linear low-density polyethylene) pre-filled oral syringe of 14 ml containing 10 gram. The syringes are closed with a LLDPE cap
Cardboard box with 1 white LLDPE (linear low-density polyethylene) pre-filled oral syringe of 14 ml containing 12 gram. The syringes are closed with a LLDPE cap
Cardboard box with 1 white LLDPE (linear low-density polyethylene) pre-filled oral syringe of 4 ml containing 3 gram. The syringes are closed with a LLDPE cap
Cardboard box with 1 white LLDPE (linear low-density polyethylene) pre-filled oral syringe of 8 ml containing 6 gram. The syringes are closed with a LLDPE cap.
Multi-pack with 12 cardboard boxes each containing 1 white LLDPE (linear low-density polyethylene) pre-filled oral syringe of 14 ml containing 10 gram. The syringes are closed with a LLDPE cap
Multi-pack with 12 cardboard boxes each containing 1 white LLDPE (linear low-density polyethylene) pre-filled oral syringe of 14 ml containing 12 gram. The syringes are closed with a LLDPE cap
Multi-pack with 12 cardboard boxes each containing 1 white LLDPE (linear low-density polyethylene) pre-filled oral syringe of 4 ml containing 3 gram. The syringes are closed with a LLDPE cap
Multi-pack with 12 cardboard boxes each containing 1 white LLDPE (linear low-density polyethylene) pre-filled oral syringe of 8 ml containing 6 gram. The syringes are closed with a LLDPE cap

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:
Le Vet. Beheer B.V.

Marketing authorisation date:
12/12/2017

Manufacturing sites for batch release:
Produlab Pharma B.V.

Responsible authority:
Swedish Medical Products Agency

Authorisation number:
54964

Date of authorisation status change:
12/12/2017

Reference member state:
Netherlands

Procedure number:
NL/V/0215/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia France Germany Greece Hungary Iceland Luxembourg Norway Poland Portugal Romania Slovakia Slovenia Sweden United Kingdom (Northern Ireland)

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

Documents

Package Leaflet

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

Summary of Product Characteristics

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