Relaquine 35 mg/ml oral gel for horses

Authorised

- Acepromazine maleate

Product identification

Medicine name:
Relaquine 35 mg/ml oral gel for horses
Plegicil Vet - Oralgel - 35 mg/ml

Active substance:
Acepromazine maleate

Target species:
Horse

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:
9 ml gel in a amber Type III glass bottle of 10 ml fitted with syringe adaptors and HDPE/LDPE CRC closure
48 ml gel in a amber Type III glass bottle of 50 ml fitted with syringe adaptors and HDPE/LDPE CRC closure
28 ml gel in a amber Type III glass bottle of 30 ml fitted with syringe adaptors and HDPE/LDPE CRC closure
15 ml gel in a white, high-density polyethylene syringe barrel and a white, low-density polyethylene syringe plunger closed with a white, high-density polyethylene, push-fit cap.
14 ml gel in a amber Type III glass bottle of 15 ml fitted with syringe adaptors and HDPE/LDPE CRC closure
18 ml gel in a amber Type III glass bottle of 20 ml fitted with syringe adaptors and HDPE/LDPE CRC closure
10 ml gel in a white, high-density polyethylene syringe barrel and a white, low-density polyethylene syringe plunger closed with a white, high-density polyethylene, push-fit cap.
10 ml gel in white, linear low-density polyethylene syringe closed with a linear low-density polyethylene, push-fit cap.
15 ml gel in white, linear low-density polyethylene syringe closed with a linear low-density polyethylene, push-fit 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:
Floris Holding B.V.

Marketing authorisation date:
26/04/2021

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

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
20-13441

Date of authorisation status change:
26/04/2021

Reference member state:
Netherlands

Procedure number:
NL/V/0303/001

Concerned member states:
Austria Belgium Denmark France Germany Norway Sweden
United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

Summary of Product Characteristics

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

Package Leaflet

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