Relaquine 35 mg/ml oral gel for horses

Authorised

- Acepromazine maleate

Product identification

Medicine name:
Relaquine 35 mg/ml oral gel for horses

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:
Germany

Package description:
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.
18 ml gel in a amber Type III glass bottle of 20 ml fitted with syringe adaptors and HDPE/LDPE CRC closure
14 ml gel in a amber Type III glass bottle of 15 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.
28 ml gel in a amber Type III glass bottle of 30 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
9 ml gel in a amber Type III glass bottle of 10 ml fitted with syringe adaptors and HDPE/LDPE CRC closure
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:
31/01/2013

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

Responsible authority:
Federal Office Of Consumer Protection And Food Safety

Authorisation number:
401876.00.00

Date of authorisation status change:
15/02/2017

Reference member state:
Netherlands

Procedure number:
NL/V/0303/001

Concerned member states:
Austria Belgium Czechia Denmark Finland France Germany Hungary Ireland Italy Norway Slovakia Spain 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

English (PDF)
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