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Sedan, 35mg/ml, Oral gel

Authorised

- Acepromazine

Product identification

Medicine name:
Sedan, 35mg/ml, Oral gel

Active substance:
Acepromazine

Target species:
Horse
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Acepromazine
35.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Oral gel

Withdrawal period by route of administration:

Oral use:

- **Horse**

  - Meat and offal. no withdrawal period

The treatment must be recorded into the horse's passport.,

  - Milk. no withdrawal period

The treatment must be recorded into the horse's passport.,

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN05AA04

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Denmark

Package description:
Plastic Applicator 1 x 10.0 millilitre(s)
Plastic Applicator 1 x 1.0 millilitre(s)

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:
Bioveta a.s.

Marketing authorisation date:

12/07/2022

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Danish Medicines Agency

Authorisation number:
67289

Date of authorisation status change:
12/07/2022

Reference member state:
Czechia

Procedure number:
CZ/V/0174/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Denmark Estonia France Germany Greece Hungary Italy Latvia Lithuania Netherlands Norway Poland Portugal Romania Slovakia Spain Sweden

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

Documents

Summary of Product Characteristics

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

Combined File of all Documents

Labelling