Recudon 2.5 mg/ml + 0.125 mg/ml solution for injection for horses and dogs

Authorised

- Levomethadone hydrochloride
- Fenpipramide hydrochloride

Product identification

Medicine name:
Recudon 2.5 mg/ml + 0.125 mg/ml solution for injection for horses and dogs
Recudon 2,5 mg/ml + 0,125 mg/ml oplossing voor injectie voor paarden en honden

Active substance:
Levomethadone hydrochloride
Fenpipramide hydrochloride

Target species:
Dog
Horse

Route of administration:
Intravenous use
Intramuscular use

Product details

Active substance and strength:
Levomethadone hydrochloride
2.50 milligram(s) / 1.00 millilitre(s)

Fenpipramide hydrochloride
0.13 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intravenous use:

- **Horse**
  - Meat and offal. 3 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN02AC52

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

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Authorisation status:
Valid

Authorised in:
Netherlands

Package description:
Cardboard box with 1 clear glass (Type I) vial of 50 ml with a coated bromobutyl rubber stopper and aluminium cap.
Cardboard box with 1 clear glass (Type I) vial of 30 ml with a coated bromobutyl rubber stopper and aluminium cap.
Cardboard box with 1 clear glass (Type I) vial of 10 ml with a coated bromobutyl rubber stopper and aluminium cap.

Cardboard box with 1 clear glass (Type I) vial of 10 ml (5 ml in a 10 ml sized vial) with a coated bromobutyl rubber stopper and aluminium cap.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 18 of Regulation (EU) 2019/6)

Marketing authorisation holder:
Alfasan Nederland B.V.

Marketing authorisation date:
10/07/2023

Manufacturing sites for batch release:
Alfasan Nederland B.V.

Responsible authority:
Medicines Evaluation Board

Authorisation number:
REG NL 129741

Date of authorisation status change:
6/02/2024

Reference member state:
Netherlands

Procedure number:
NL/V/0384/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Norway Poland Portugal Romania Slovakia Slovenia Spain

Sweden United Kingdom (Northern Ireland)

Generic of:
600000004401

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

Documents

Combined File of all Documents

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