Recudon 5 mg/ml + 0.25 mg/ml solution for injection for horses and dogs

Authorised

- Levomethadone hydrochloride
- Fenpipramide hydrochloride

Product identification

Medicine name:
Recudon 5 mg/ml + 0.25 mg/ml solution for injection for horses and dogs
RECUDON 4,4 MG/ML + 0,22 MG/ML SOLUTION INJECTABLE POUR CHEVAUX ET CHIENS

Active substance:
Levomethadone hydrochloride
Fenpipramide hydrochloride

Target species:
Horse
Dog

Route of administration:
Intravenous use

Product details

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

Fenpipramide hydrochloride
0.25 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:
France

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 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:
Hybrid application – change in strength (Article 19(1)(a) of Regulation (EU) 2019/6)

Marketing authorisation holder:
Alfasan Nederland B.V.

Marketing authorisation date:
6/05/2025

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

Responsible authority:
French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:
FR/V/3537662 2/2023

Date of authorisation status change:
6/05/2025

Reference member state:
Netherlands

Procedure number:
NL/V/0384/002

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

Sweden United Kingdom (Northern Ireland)

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.

Package Leaflet and Labelling

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

Combined File of all Documents