

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 5 mg/ml + 0,25 mg/ml soluzione iniettabile per cavalli e cani

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

Authorisation status:

Valid

Authorised in:

Italy

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:

30/10/2023

Manufacturing sites for batch release:

Alfasan Nederland B.V.

Responsible authority:

Ministry Of Health

Authorisation number:

105692

Date of authorisation status change:

30/10/2023

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

Combined File of all Documents

English (PDF)

Published on: 27/12/2025

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Summary of Product Characteristics

Package Leaflet and Labelling