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

Authorised

• Levomethadone

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 solution for injection for horses and dogs

Active substance:

Levomethadone

Target species:

Dog Horse

Route of administration:

Intravenous use Intramuscular use

Product details

Active substance and strength:

Levomethadone 2.20 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Intravenous use:

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

Intramuscular use:

• Dog

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QN02AC52

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Ireland

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:

17/07/2023

Manufacturing sites for batch release:

Alfasan Nederland B.V.

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA10980/027/001

Date of authorisation status change:

17/07/2023

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)

This information is not available for this product.

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

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