

Dormostart 1 mg/ml solution for injection for dogs and cats

Authorised

- Medetomidine hydrochloride

Product identification

Medicine name:

Dormostart 1 mg/ml solution for injection for dogs and cats

Active substance:

Medetomidine hydrochloride

Target species:

Dog

Cat

Route of administration:

Intramuscular use

Intramuscular use

Intravenous use

Product details

Active substance and strength:

Medetomidine hydrochloride

1.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QN05CM91

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Ireland

Package description:

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

Cardboard box with one clear Type I glass vial of 10 ml with grey fluorinated coated bromobutyl rubber stopper and aluminium cap.

Cardboard box with one clear Type I glass vial of 20 ml with grey fluorinated 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:

13/10/2023

Manufacturing sites for batch release:

Alfasan Nederland B.V.

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA10980/033/001

Date of authorisation status change:

13/10/2023

Reference member state:

Netherlands

Procedure number:

NL/V/0401/001

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:

600000063843

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

Documents

Summary of Product Characteristics

Dormostart, REG NL 130486 - Public Assessment Report - MEBa updated
20260126.pdf