

# Dexdormostart 0.5 mg/ml solution for injection for dogs and cats

Authorised

- Dexmedetomidine hydrochloride

## Product identification

**Medicine name:**

Dexdormostart 0.5 mg/ml solution for injection for dogs and cats

---

**Active substance:**

Dexmedetomidine hydrochloride

---

**Target species:**

Dog

Cat

---

**Route of administration:**

Intramuscular use

Intramuscular use

Intravenous use

---

## Product details

**Active substance and strength:**

Dexmedetomidine hydrochloride

0.50 milligram(s) / 1.00 millilitre(s)

---

**Pharmaceutical form:**

Solution for injection

---

**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QN05CM18

---

**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

---

**Authorisation status:**

Valid

---

**Authorised in:**

Cyprus

---

**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:**

31/10/2023

---

**Manufacturing sites for batch release:**

Alfasan Nederland B.V.

---

**Responsible authority:**

Veterinary Services, Ministry Of Agriculture, Natural Resources And Environment

---

**Authorisation number:**

CY00930V

---

**Date of authorisation status change:**

31/10/2023

---

**Reference member state:**

Netherlands

---

**Procedure number:**

NL/V/0400/001

---

**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:**

600000003547

---

To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

Combined File of all Documents

English (PDF)

Published on: 14/12/2023

Download

Summary of Product Characteristics

PuAR Dexdormostart NL-V-0400-001-DC.pdf