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:
France

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:
26/10/2023

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

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

Authorisation number:
FR/V/7111393 3/2023

Date of authorisation status change:
26/10/2023

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

Documents

Package Leaflet and Labelling

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

Summary of Product Characteristics

English (PDF)
Published on: 25/03/2026
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Combined File of all Documents

English (PDF)
Published on: 14/03/2026
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PuAR Dexdormostart NL-V-0400-001-DC.pdf