

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:

Slovakia

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:

29/05/2024

Manufacturing sites for batch release:

Alfasan Nederland B.V.

Responsible authority:

Institute For State Control Of Veterinary Biologicals And Medicaments

Authorisation number:

96/027/DC/24-S

Date of authorisation status change:

29/05/2024

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

Combined File of all Documents

English (PDF)

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Summary of Product Characteristics

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