Sileo 0.1 mg/ml - oromucosal gel

Authorised

- Dexmedetomidine hydrochloride

Product identification

Medicine name:
Sileo 0.1 mg/ml - oromucosal gel

Active substance:
Dexmedetomidine hydrochloride

Target species:
Dog

Route of administration:
Oromucosal use

Product details

Active substance and strength:
Dexmedetomidine hydrochloride
0.11 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Oromucosal gel

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN05CM18

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Austria , Belgium , Bulgaria , Croatia , Cyprus , Czechia , Denmark , Estonia , Finland , France , Germany , Greece , Hungary , Iceland , Ireland , Italy , Latvia , Liechtenstein , Lithuania , Luxembourg , Malta , Netherlands , Norway , Poland , Portugal , Romania , Slovakia , Slovenia , Spain , Sweden , United Kingdom (Northern Ireland)

Available in:
Austria , Belgium , Bulgaria , Croatia , Cyprus , Czechia , Denmark , Estonia , Finland , France , Germany , Greece , Hungary , Ireland , Italy , Latvia , Lithuania , Luxembourg , Netherlands , Norway , Poland , Portugal , Romania , Slovakia , Slovenia , Spain , Sweden , United Kingdom (Northern Ireland)

Package description:
Packaging:pre-filled syringe (HDPE), Package_size:5 (5x1) pre-filled syringes (multipack), Content:3 ml
Packaging:pre-filled syringe (HDPE), Package_size:10 (10x1) pre-filled syringes (multipack), Content:3 ml
Packaging:pre-filled syringe (HDPE), Package_size:3 (3x1) pre-filled syringes (multipack), Content:3 ml
Packaging:pre-filled syringe (HDPE), Package_size:20 (20x1) pre-filled syringes(multipack), Content:3 ml
Packaging:pre-filled syringe (HDPE), Package_size:1 pre-filled syringe, Content:3 ml

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application - Known active substance (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Orion Corporation

Marketing authorisation date:
10/06/2015

Manufacturing sites for batch release:
Orion Corporation

Responsible authority:
European Commission

Authorisation number:
This information is not available for this product.

Date of authorisation status change:
10/06/2015

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

Documents

Combined File of all Documents

English (PDF)
Published on: 27/02/2026
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ema-puar-v3764-sileo-initial-en.pdf

ema-puar-v3764-sileo-withdrawal-var-ii0022-2023-08-29-en.pdf