

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)

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