Fentadon 50 microgram/ml, solution for injection for dogs

Authorised

- Fentanyl citrate

Product identification

Medicine name:
Fentadon 50 microgram/ml, solution for injection for dogs
Fentadon 50 microgram/ml oplossing voor injectie voor honden

Active substance:
Fentanyl citrate

Target species:
Dog

Route of administration:
Intravenous use

Product details

Active substance and strength:
Fentanyl citrate
78.50 microgram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection/infusion

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN02AB03

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

Authorisation status:
Valid

Authorised in:
Netherlands

Package description:
Vial of uncoloured glass type I, filled with 10 ml. Teflon-coated chlorobutyl rubber stoppers type I secured with aluminium caps.
Vial of uncoloured glass type I, filled with 100 ml. Teflon-coated chlorobutyl rubber stoppers type I secured with aluminium caps.
Vial of uncoloured glass type I, filled with 50 ml. Teflon-coated chlorobutyl rubber stoppers type I secured with aluminium caps.
Vial of uncoloured glass type I, filled with 5 ml. Teflon-coated chlorobutyl rubber stoppers type I secured with aluminium caps.
Vial of uncoloured glass type I, filled with 30 ml. Teflon-coated chlorobutyl rubber stoppers type I secured with aluminium caps.
Vial of uncoloured glass type I, filled with 25 ml. Teflon-coated chlorobutyl rubber stoppers type I secured with aluminium caps.
Vial of uncoloured glass type I, filled with 20 ml. Teflon-coated chlorobutyl rubber stoppers type I secured with aluminium caps.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Well-established use application (Article 13a of Directive No 2001/82/EC)

Marketing authorisation holder:
Eurovet Animal Health B.V.

Marketing authorisation date:
7/03/2012

Manufacturing sites for batch release:
Eurovet Animal Health B.V.

Responsible authority:
Medicines Evaluation Board

Authorisation number:
REG NL 108332

Date of authorisation status change:
28/01/2022

Reference member state:
Netherlands

Procedure number:
NL/V/0155/001

Concerned member states:
Austria Belgium Denmark France Germany Italy Luxembourg Norway Poland Portugal Spain Sweden United Kingdom (Northern Ireland)

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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