Comfortan 10 mg/ml solution for injection for dogs and cats

Authorised

- Methadone hydrochloride

Product identification

Medicine name:
Comfortan 10 mg/ml solution for injection for dogs and cats

Active substance:
Methadone hydrochloride

Target species:
Dog
Cat

Route of administration:
Intramuscular use
Intravenous use
Subcutaneous use

Product details

Active substance and strength:
Methadone hydrochloride
10.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN02AC90

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

Authorisation status:
Valid

Authorised in:
Norway

Available in:
Norway

Package description:
Cardboard box containing 1 vial (uncoloured glass type I, closed teflon-coated chlorobutyl rubber stopper type I, secured with an aluminium cap) filled with 50 ml
Cardboard box containing 1 vial (uncoloured glass type I, closed teflon-coated chlorobutyl rubber stopper type I, secured with an aluminium cap) filled with 5 ml
Cardboard box containing 1 vial (uncoloured glass type I, closed teflon-coated chlorobutyl rubber stopper type I, secured with an aluminium cap) filled with 30 ml
Cardboard box containing 1 vial (uncoloured glass type I, closed teflon-coated chlorobutyl rubber stopper type I, secured with an aluminium cap) filled with 25 ml
Cardboard box containing 1 vial (uncoloured glass type I, closed teflon-coated chlorobutyl rubber stopper type I, secured with an aluminium cap) filled with 20 ml
Cardboard box containing 1 vial (uncoloured glass type I, closed teflon-coated chlorobutyl rubber stopper type I, secured with an aluminium cap) filled with 10 ml

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:

Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Eurovet Animal Health B.V.

Marketing authorisation date:
4/10/2016

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

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
16-11127

Date of authorisation status change:
21/06/2021

Reference member state:
Netherlands

Procedure number:
NL/V/0150/001

Concerned member states:
Austria Belgium Bulgaria Croatia Denmark Finland France Germany Ireland Italy Norway Poland Portugal Slovenia Spain Sweden

United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

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

Combined File of all Documents

PuAR Comfortan REG NL 107389 _updated 20230831.pdf