Bupredine Multidose 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses

Authorised

- Buprenorphine hydrochloride

Product identification

Medicine name:
Bupredine Multidose 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses
Bupredine Multidose vet., 0,3mg/ml, Injekční roztok

Active substance:
Buprenorphine hydrochloride

Target species:
Dog
Horse
Cat

Route of administration:
Intramuscular use
Intravenous use

Product details

Active substance and strength:
Buprenorphine hydrochloride
0.32 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Dog**
- **Horse**
- **Cat**

Intravenous use:

- **Dog**
- **Horse**
- **Cat**

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QN02AE01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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Authorisation status:

Valid

Authorised in:

Czechia

Package description:

Clear type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box. Pack size: 20 ml.
Clear type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box. Pack size: 100 ml
Clear type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box. Pack size: 10 ml.
Clear type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box. Pack size: 50 ml
Clear type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box. Pack size: 5 ml.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
Le Vet. Beheer B.V.

Marketing authorisation date:
25/05/2016

Manufacturing sites for batch release:
Produlab Pharma B.V.

Responsible authority:
Institute For State Control Of Veterinary Biologicals And Medicaments

Authorisation number:
96/037/16-C

Date of authorisation status change:
25/05/2016

Reference member state:
Netherlands

Procedure number:
NL/V/0314/001

Concerned member states:
Austria Belgium Croatia Cyprus Czechia Denmark Estonia France Germany Greece Hungary Iceland Latvia Lithuania Luxembourg Norway Poland Portugal Romania Slovakia 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

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Package Leaflet

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

Labelling

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

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