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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

Active substance:
Buprenorphine hydrochloride

Target species:
Dog
Cat
Horse

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:
Intravenous use:

- **Horse**
  - All relevant tissues. no withdrawal period

Not authorised for use in horses intended for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN02AE01

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

Authorisation status:
Valid

Authorised in:
Norway

Package description:
Clear type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box. Pack size: 5 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: 10 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: 20 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:
3/10/2016

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

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
14-10372

Date of authorisation status change:
23/09/2020

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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Combined File of all Documents