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Detogesic 10 mg/ml Solution for Injection for Horses

Authorised

- DETOMIDINE HYDROCHLORIDE FOR VETERINARY USE

Product identification

Medicine name:
Detogesic 10 mg/ml Solution for Injection for Horses

Active substance:
DETOMIDINE HYDROCHLORIDE FOR VETERINARY USE

Target species:
Horse

Route of administration:
Intravenous use

Product details

Active substance and strength:
DETOMIDINE HYDROCHLORIDE FOR VETERINARY USE
10.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:

Intravenous use:

- **Horse**
  - Meat and offal. 2 day
  - Milk. 12 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN05CM90

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

Authorisation status:
Valid

Authorised in:
Germany

Available in:
Germany

Package description:
Multidose, clear, Type I glass injection vial containing 10 ml solution which may be closed with either a red bromobutyl rubber stopper or grey chlorobutyl rubber stopper, secured with an aluminium crimp.
Multidose, clear, cyclic olefin copolymer injection vial containing 15 ml solution, which may be closed with either a red bromobutyl rubber stopper or grey chlorobutyl rubber stopper, secured with an aluminium crimp.

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:
Vetcare Oy

Marketing authorisation date:
28/03/2008

Manufacturing sites for batch release:
Laboratorios Syva S.A.

Responsible authority:
Federal Office Of Consumer Protection And Food Safety

Authorisation number:
400988.00.00

Date of authorisation status change:
13/06/2013

Reference member state:
Finland

Procedure number:
FI/V/0112/001

Concerned member states:
Austria Belgium Bulgaria Cyprus Czechia Denmark Estonia France Germany Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

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Documents

Combined File of all Documents

English (PDF)
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