PENETHAONE Powder and solvent for suspension for injection for cattle

Authorised

Penethamate hydriodide

Product identification

Medicine name:

PENETHAONE Powder and solvent for suspension for injection for cattle Penethaone 236,3 mg/ml прах и разтворител за инжекционна суспензия за говеда

Active substance:

Penethamate hydriodide

Target species:

Cattle (lactating cow)

Route of administration:

Intramuscular use

Product details

Active substance and strength:

Penethamate hydriodide 236.30 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Withdrawal period by route of administration:

Intramuscular use:

- Cattle (lactating cow)
 - Meat and offal. 4 day
 - Milk. no withdrawal period Meat and offal: 4 days; Milk: 2,5 days/60 hours.

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01CE90

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Bulgaria

Package description:

box containing $10 \times 10,000,000$ IU powder vial and 10×36 ml solvent vial box containing $5 \times 10,000,000$ IU powder vial and 5×36 ml solvent vial box containing $1 \times 10,000,000$ IU powder vial and 1×36 ml solvent vial box containing $10 \times 5,000,000$ IU powder vial and 10×18 ml solvent vial box containing $5 \times 5,000,000$ IU powder vial and 5×18 ml solvent vial box containing $1 \times 5,000,000$ IU powder vial and 1×18 ml solvent vial

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:



Marketing authorisation date:

14/05/2015

Manufacturing sites for batch release:

Divasa Farmavic S.A.

Responsible authority:

Bulgarian Food Safety Authority

Authorisation number:

0022-2554

Date of authorisation status change:

10/05/2020

Reference member state:

Spain

Procedure number:

ES/V/0226/001

Concerned member states:

Austria Belgium Bulgaria Czechia Denmark France Germany Greece Hungary Iceland Ireland Italy Lithuania Netherlands Norway Poland Portugal Romania Slovakia 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

English (PDF)

Published on: 26/12/2023

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Package Leaflet and Labelling

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