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Stellamune Once Emulsion for injection

Authorised

- Mycoplasma hyopneumoniae, strain NL1042, Inactivated

Product identification

Medicine name:
Stellamune Once Emulsion for injection

Active substance:
Mycoplasma hyopneumoniae, strain NL1042, Inactivated

Target species:
Pig

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Mycoplasma hyopneumoniae, strain NL1042, Inactivated
4.50 log10 relative potency / 1.00 Dose

Pharmaceutical form:
Emulsion for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Pig**
  - Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI09AB13

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

Authorisation status:
Valid

Authorised in:
Germany

Available in:
Germany

Package description:
(ID2) 500 Dose: Box (cardboard) with 10 Bottle (high-density polyethylene) each with 50 Dose, closed with Stopper (chlorobutyl rubber)
(ID3) 500 Dose: Box (cardboard) with 4 Bottle (high-density polyethylene) each with 125 Dose, closed with Stopper (chlorobutyl rubber)

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Immunological veterinary medicinal product application (Article 13d of Directive No 2001/82/EC)

Marketing authorisation holder:

Elanco GmbH

Marketing authorisation date:
5/06/2002

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

Responsible authority:
Paul-Ehrlich-Institut

Authorisation number:
PEI.V.02633.01.1

Date of authorisation status change:
5/11/2007

Reference member state:
Germany

Procedure number:
DE/V/0281/001

Concerned member states:
Austria Belgium Bulgaria Denmark France Greece Iceland Italy Luxembourg Netherlands Norway Portugal Romania Spain Sweden

United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

English (PDF)

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