Source URL: https://medicines.health.europa.eu/veterinary/en/600000061668

Stellamune Once Emulsion for injection

Authorised

Mycoplasma hyopneumoniae, strain NL1042, Inactivated

Product identification

Medicine name:

Stellamune Once Emulsion for injection Stellamune One

Active substance:

Mycoplasma hyopneumoniae, strain NL1042, Inactivated

Target species:

Pig

Pig (for fattening)

Pig (suckling piglet)

Route of administration:

Intramuscular use

Product details

Active substance and strength:

Mycoplasma hyopneumoniae, strain NL1042, Inactivated 4.50 log10 ELISA unit / 2.00 millilitre(s)

Pharmaceutical form:

Emulsion for injection

Withdrawal period by route of administration:

Intramuscular use:

Pig

- Meat and offal. 0 day

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Pig (for fattening)

- Meat and offal. 0 day

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Pig (suckling piglet)

- 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:

(ID3): 1 Box with 4 Bottle (High Density PolyEthylene) with 250 millilitre(s), 125 ID (1000 millilitre(s), 500 ID)

(ID2): 1 Box with 10 Bottle (High Density PolyEthylene) with 100 millilitre(s), 50 ID (1000 millilitre(s), 500 ID)

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:

Zoetis Belgium

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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