

# Stellamune Once Emulsion for injection

Authorised

- Mycoplasma hyopneumoniae, strain NL1042, Inactivated

## Product identification

**Medicine name:**

Stellamune Once Emulsion for injection

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**Active substance:**

Mycoplasma hyopneumoniae, strain NL1042, Inactivated

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**Target species:**

Pig

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**Route of administration:**

Intramuscular use

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## Product details

**Active substance and strength:**

Mycoplasma hyopneumoniae, strain NL1042, Inactivated  
4.50 log<sub>10</sub> relative potency / 1.00 Dose

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**Pharmaceutical form:**

Emulsion for injection

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**Withdrawal period by route of administration:****Intramuscular use:**

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**Pig**

- Meat and offal. 0 day

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QI09AB13

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Belgium

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**Available in:**

Belgium

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**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)

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

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

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**Marketing authorisation holder:**

Elanco GmbH

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**Marketing authorisation date:**

26/08/2002

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**Manufacturing sites for batch release:**

Laboratorios Syva S.A.

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**Responsible authority:**

Federal Agency For Medicines And Health Products

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**Authorisation number:**

BE-V239933

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**Date of authorisation status change:**

26/08/2002

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**Reference member state:**

Germany

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**Procedure number:**

DE/V/0281/001

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**Concerned member states:**

Austria Belgium Bulgaria Denmark France Greece Iceland Italy Luxembourg  
Netherlands Norway Portugal Romania Spain Sweden  
United Kingdom (Northern Ireland)

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents

Labelling

This document does not exist in this language (English). You can find it in another language below.