# Stellamune Once Emulsion for injection

Authorised

• Mycoplasma hyopneumoniae, strain NL1042, Inactivated

## Product identification

#### **Medicine name:**

Stellamune Once Emulsion for injection Stellamune One, injeksjonsvæske, emulsjon til gris.

#### **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 0.72 enzyme-linked immunosorbent assay unit / 2.00 millilitre(s)

#### **Pharmaceutical form:**

**Emulsion for injection** 

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

- Pig
  - Meat and offal. 0 day
- Pig (for fattening)
  - Meat and offal. 0 day
- 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:

Norway

## 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)

(ID1): 1 Box with 10 Bottles (High Density PolyEthylene) with 20 millilitre(s), 10 ID (200 millilitre(s), 100 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:

This information is not available for this product.

## Manufacturing sites for batch release:

Zoetis Belgium

Laboratorios Syva S.A.U.

#### **Responsible authority:**

Norwegian Medical Products Agency

#### **Authorisation number:**

02-1011

#### Date of authorisation status change:

23/05/2007

#### **Reference member state:**

Germany

#### **Procedure number:**

DE/V/0281/001

#### **Concerned member states:**

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

To consult adverse reactions on veterinary medicinal products please go to <a href="https://www.adrreports.eu/vet">www.adrreports.eu/vet</a>

## **Documents**

Summary of Product Characteristics

English (PDF)

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