BIOSUIS APP 2, 9, 11, Emulsion for injection

Authorised

- Actinobacillus pleuropneumoniae, serovar 2, strain WSLB 3012, Inactivated
- Actinobacillus pleuropneumoniae, serovar 9, strain WSLB 3013, Inactivated
- Actinobacillus pleuropneumoniae, serovar 11, Inactivated
- Actinobacillus pleuropneumoniae, APX I toxoid
- Actinobacillus pleuropneumoniae, APX II toxoid
- Actinobacillus pleuropneumoniae, APX III toxoid

Product identification

Medicine name:
BIOSUIS APP 2, 9, 11, Emulsion for injection

Active substance:
Actinobacillus pleuropneumoniae, serovar 2, strain WSLB 3012, Inactivated
Actinobacillus pleuropneumoniae, serovar 9, strain WSLB 3013, Inactivated
Actinobacillus pleuropneumoniae, serovar 11, Inactivated
Actinobacillus pleuropneumoniae, APX I toxoid
Actinobacillus pleuropneumoniae, APX II toxoid
Actinobacillus pleuropneumoniae, APX III toxoid

Target species:
Pig

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Actinobacillus pleuropneumoniae, serovar 2, strain WSLB 3012, Inactivated
1.00 relative potency / 1.00 Dose

Actinobacillus pleuropneumoniae, serovar 9, strain WSLB 3013, Inactivated
1.00 relative potency / 1.00 Dose

Actinobacillus pleuropneumoniae, serovar 11, Inactivated
1.00 relative potency / 1.00 Dose

Actinobacillus pleuropneumoniae, APX I toxoid
1.00 relative potency / 1.00 Dose

Actinobacillus pleuropneumoniae, APX II toxoid
1.00 relative potency / 1.00 Dose

Actinobacillus pleuropneumoniae, APX III toxoid
1.00 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:
QI09AB07

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

Authorisation status:

Valid

Authorised in:
Greece

Package description:
Glass Vial 1 x 10.0 Dose
Glass Vial 1 x 50.0 Dose
Glass Vial 1 x 100.0 Dose
Plastic Vial 1 x 10.0 Dose
Plastic Vial 1 x 50.0 Dose
Plastic Vial 1 x 100.0 Dose
Plastic Bottle 1 x 250.0 Dose
Glass Vial 10 x 10.0 millilitre(s) - outer container: cardboard box
Plastic Vial 10 x 10.0 millilitre(s) - outer container: cardboard box
Glass Vial 10 x 10.0 millilitre(s) outer container: plastic box
Plastic Vial 10 x 10.0 millilitre(s) - outer container: plastic box

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Bioveta a.s.

Marketing authorisation date:
7/12/2017

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
National Organization For Medicines

Authorisation number:

70290/28-06-2022/K-0227501

Date of authorisation status change:
27/06/2022

Reference member state:
Czechia

Procedure number:
CZ/V/0121/001

Concerned member states:
Croatia Estonia Greece Hungary Latvia Lithuania Poland Romania Slovakia

To consult adverse reactions on veterinary medicinal products please go to 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.

Labelling

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

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