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:
Croatia

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:
16/03/2018

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Ministry Of Agriculture Veterinary And Food Safety Directorate

Authorisation number:

UP/I-322-05/17-01/475

Date of authorisation status change:
16/03/2018

Reference member state:
Czechia

Procedure number:
CZ/V/0121/001

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

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

Documents

Summary of Product Characteristics

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