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ENTERICOLIX, emulsion for injection for pigs

Authorised

- Escherichia coli, serotype O141:K85ab (fimbrial adhesin F6), strain P4, Inactivated
- Escherichia coli, serotype O101 (fimbrial adhesin F5 and F41), strain P10, Inactivated
- Escherichia coli, serotype O138:K81 (fimbrial adhesin F18ab), strain P5, Inactivated
- Escherichia coli, serotype O149:K91:H10 (fimbrial adhesin F4ac), strain P6, Inactivated
- Escherichia coli, serotype O157:H39 (fimbrial adhesin F18ac), strain P9, Inactivated
- Clostridium perfringens, type C, beta toxoid

Product identification

Medicine name:
ENTERICOLIX, emulsion for injection for pigs

Active substance:
Escherichia coli, serotype O141:K85ab (fimbrial adhesin F6), strain P4, Inactivated

Escherichia coli, serotype O101 (fimbrial adhesin F5 and F41), strain P10, Inactivated

Escherichia coli, serotype O138:K81 (fimbrial adhesin F18ab), strain P5, Inactivated

Escherichia coli, serotype O149:K91:H10 (fimbrial adhesin F4ac), strain P6, Inactivated

Escherichia coli, serotype O157:H39 (fimbrial adhesin F18ac), strain P9, Inactivated

Clostridium perfringens, type C, beta toxoid

Target species:
Pig (sow, multipar)
Pig (sow, primipar)

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Escherichia coli, serotype O141:K85ab (fimbrial adhesin F6), strain P4, Inactivated
1.00 relative potency / 2.00 millilitre(s)

Escherichia coli, serotype O101 (fimbrial adhesin F5 and F41), strain P10, Inactivated
1.00 relative potency / 2.00 millilitre(s)

Escherichia coli, serotype O138:K81 (fimbrial adhesin F18ab), strain P5, Inactivated
1.00 relative potency / 2.00 millilitre(s)

Escherichia coli, serotype O149:K91:H10 (fimbrial adhesin F4ac), strain P6, Inactivated
1.00 relative potency / 2.00 millilitre(s)

Escherichia coli, serotype O157:H39 (fimbrial adhesin F18ac), strain P9, Inactivated
1.00 relative potency / 2.00 millilitre(s)

Clostridium perfringens, type C, beta toxoid
10.00 Toxicity unit(s) / 2.00 millilitre(s)

Pharmaceutical form:
Emulsion for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Pig (sow, multipar)**
  - Meat and offal. 0 day
-

Pig (sow, primipar)

- Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI09AB08

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

Authorisation status:
Valid

Authorised in:
Germany

Package description:
box containing 1 bottle of 50 ml (25 doses)

Additional information

Entitlement type:
Marketing Authorisation

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

Marketing authorisation holder:
CZ Vaccines S.A.U.

Marketing authorisation date:
8/03/2016

Manufacturing sites for batch release:
CZ Vaccines S.A.U.

Responsible authority:
Paul-Ehrlich-Institut

Authorisation number:

PEI.V.11739.01.1

Date of authorisation status change:
29/10/2020

Reference member state:
Spain

Procedure number:
ES/V/0228/001

Concerned member states:
Austria Belgium Bulgaria Cyprus Czechia Denmark France Germany Greece Hungary Ireland Italy Netherlands Poland Portugal Romania Slovakia Slovenia United Kingdom (Northern Ireland)

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

Documents

Labelling

Combined File of all Documents

English (PDF)
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