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Fencovis, Suspension for injection

Authorised

- Escherichia coli, serotype O8:K35 (fimbrial adhesin F5), Inactivated
- Bovine coronavirus, strain C-197, Inactivated
- Bovine rotavirus A, type G6P1, strain TM-91, Inactivated

Product identification

Medicine name:
Fencovis, Suspension for injection

Active substance:
Escherichia coli, serotype O8:K35 (fimbrial adhesin F5), Inactivated

Bovine coronavirus, strain C-197, Inactivated

Bovine rotavirus A, type G6P1, strain TM-91, Inactivated

Target species:
Cattle

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Escherichia coli, serotype O8:K35 (fimbrial adhesin F5), Inactivated
1.00 relative potency / 1.00 Dose

Bovine coronavirus, strain C-197, Inactivated
1.00 relative potency / 1.00 Dose

Bovine rotavirus A, type G6P1, strain TM-91, Inactivated
1.00 relative potency / 1.00 Dose

Pharmaceutical form:
Suspension for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. 0 day
  - Milk. 0 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI02AL01

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

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Authorisation status:
Valid

Authorised in:
Germany

Available in:
Germany

Package description:
Glass Vial 20 x 1.0 Dose
Glass Vial 10 x 1.0 Dose
Glass Vial 2 x 1.0 Dose
Plastic Vial 1 x 50.0 Dose
Glass Vial 1 x 50.0 Dose
Plastic Vial 24 x 25.0 Dose
Glass Vial 24 x 25.0 Dose

Plastic Vial 12 x 25.0 Dose
Glass Vial 12 x 25.0 Dose
Plastic Vial 1 x 25.0 Dose
Glass Vial 1 x 25.0 Dose
Plastic Vial 10 x 5.0 Dose
Glass Vial 10 x 5.0 Dose
Plastic Vial 5 x 5.0 Dose
Glass Vial 5 x 5.0 Dose
Plastic Vial 1 x 5.0 Dose
Glass Vial 1 x 5.0 Dose

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:
Boehringer Ingelheim Vetmedica GmbH

Marketing authorisation date:
23/08/2022

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Paul-Ehrlich-Institut

Authorisation number:
PEI.V.12116.01.1

Date of authorisation status change:
23/08/2022

Reference member state:
Czechia

Procedure number:
CZ/V/0177/001

Concerned member states:
Austria Belgium Finland France Germany Greece Ireland Italy Luxembourg Netherlands Norway Portugal Spain Sweden
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

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7005790-paren-20220501.pdf