1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fencovis suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Escherichia coli, serotype O8:K35 (fimbrial adhesin F5), Inactivated	RP*≥ 1
Bovine rotavirus, serotype G6P1, strain TM-91, Inactivated	RP*≥ 1
Bovine coronavirus, strain C-197, Inactivated	RP*≥ 1

* Relative potency (RP): level of antibodies in sera of vaccinated guinea pigs as determined by ELISA in comparison with the reference serum obtained after vaccination of guinea pigs with a vaccine batch that has successfully passed the challenge test in cattle.

Adjuvants:

Aluminium hydroxide	3 mg
Quillaja saponin (Quil A)	≤ 0.2 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.1 mg
Formaldehyde	
Sodium chloride	
Potassium chloride	
Potassium dihydrogen phosphate	
Disodium phosphate dodecahydrate	
Water for injection	

Orange, pink to deep pink liquid with whitish sediment, which is homogenously dispersed after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

Cattle
Active immunisation of pregnant heifers and cows in order to stimulate the development of antibodies against bovine rotavirus, bovine coronavirus and *E. coli* expressing F5 (K99) adhesin and to increase the level of passive immunity of calves against neonatal diarrhoea caused by bovine rotavirus, bovine coronavirus and *E. coli* expressing F5 (K99) adhesin.

In calves fed with colostrum and milk from vaccinated dams for the first week of life, laboratory studies conducted with heterologous challenge strains (a G6 BRV strain, a BCV strain and a K99 *E. coli* strain) have demonstrated that these antibodies:

- prevent neonatal diarrhoea caused by bovine rotavirus and *E. coli* expressing F5 (K99) adhesin,
- reduce the incidence and severity of neonatal diarrhoea caused by bovine coronavirus,
- reduce faecal shedding of virus in calves infected with bovine rotavirus and bovine coronavirus.

Onset of immunity:
In calves fed with colostrum from vaccinated dams, passive immunity commences with colostrum feeding and is dependent on calves receiving sufficient colostrum after birth.

Duration of immunity:
Calves fed with colostrum and milk from vaccinated dams for the first week of life are protected against bovine rotavirus for 7 days and against bovine coronavirus for 14 days.
The duration of immunity against infections caused by *E. coli* expressing F5 (K99) adhesin was not studied since such disease is usually observed in calves less than 3 days of age and susceptibility to enterotoxigenic *E. coli* is age dependent.

Sheep
Active immunisation of pregnant ewes in order to stimulate the development of antibodies against bovine rotavirus and *E. coli* expressing F5 (K99) adhesin and to increase the level of passive immunity of lambs against neonatal diarrhoea caused by bovine rotavirus and *E. coli* expressing F5 (K99) adhesin.

In lambs fed with colostrum and milk from vaccinated dams for the first week of life, laboratory studies conducted with heterologous challenge strains (a G6 BRV strain and a K99 *E. coli* strain) have demonstrated that these antibodies:

- reduce neonatal diarrhoea caused by bovine rotavirus and *E. coli* expressing F5 (K99) adhesin,
- reduce faecal shedding of virus in lambs infected with bovine rotavirus.

Onset of immunity:
In lambs fed with colostrum from vaccinated dams, passive immunity commences with colostrum feeding and is dependent on lambs receiving sufficient colostrum after birth.

Duration of immunity:
Lambs fed with colostrum and milk from vaccinated dams for the first week of life are protected against bovine rotavirus for 7 days.
The duration of immunity against infections caused by *E. coli* expressing F5 (K99) adhesin was not studied since such disease is usually observed in lambs less than 3 days of age and susceptibility to enterotoxigenic *E. coli* is age dependent.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
To achieve optimum results and to reduce infection pressure on the farm, a whole herd cow/ewe vaccination policy should be adopted, as well as standard infectious diseases control practices.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of adverse reactions following accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle

Very common (>1 animal / 10 animals treated):	Elevated temperature[1].
Common (1 to 10 animals / 100 animals treated):	Injection site swelling[2].

[1] Mean increase of 1.0 °C that may reach 2.1 °C in individual cases, resolving within 2 days.
[2] Up to 5 cm in diameter, mild, resolving within 2 days.

Sheep

Very common (>1 animal / 10 animals treated):	Elevated temperature[1].

[1] Mean increase of 0.8 °C that may reach 1.25 °C in individual cases, resolving within 2 days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy.
The effect of vaccination on pre- or post-partum lactation was not studied.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

3.9 Administration route and dosage

Cattle

Intramuscular use.

Slowly warm up to room temperature and gently shake the content of the vial before administration.

Administration:
One dose of 2 ml by intramuscular injection.
A single injection should be given during each pregnancy between 12 and 3 weeks before the expected calving.

Colostrum feeding:
Calves are born without protection from antibodies. Immunity against neonatal diarrhoea is provided by rapid uptake of colostral antibodies from vaccinated dams. The first colostrum intake should take place as soon as possible, ideally within 2 hours and at most 6 hours after birth. In dairy calves, it should represent a volume equivalent to approximately 10% of the body weight, followed by a similar volume within 12 hours. Beef calves should stand and suckle within 2 hours of calving.

Sheep

Subcutaneous use.

Slowly warm up to room temperature and gently shake the content of the vial before administration.

Administration:
One dose of 1 ml by subcutaneous injection.
A single injection should be given during each pregnancy between 6 and 3 weeks before the expected lambing.

Colostrum feeding:
Lambs are born without protection from antibodies. Immunity against neonatal diarrhoea is provided by rapid uptake of colostral antibodies from vaccinated dams. The first colostrum intake should take place as soon as possible, ideally within 2 hours and at most 6 hours after birth. During the first day of life, lambs should receive at least 10% of their body weight in colostrum, divided into several feedings.

3.10 Symptoms of overdose (and where applicable, emergency procedures, antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AL01(cattle) and QI04AL (sheep)

Vaccination of pregnant heifers and cows induces specific antibodies that are present at high levels from 3 to 12 weeks after vaccination for passive immunisation of calves via colostrum intake against bovine rotavirus, bovine coronavirus and *E. coli* expressing F5 (K99) adhesin.

Vaccination of pregnant ewes induces specific antibodies that are present at high levels from 3 to 6 weeks after vaccination for passive immunisation of lambs via colostrum intake against bovine rotavirus and *E. coli* expressing F5 (K99) adhesin.
Vaccination of pregnant ewes induces specific antibodies that are present at high levels from 3 to 6 weeks after vaccination which results in passive transfer of antibodies against bovine coronavirus; however, the clinical benefit of this transfer in lambs has not been investigated.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 10 hours.

5.3. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Once open, the vials should not be stored above 25 °C.
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I glass vials of 3 or 10 ml with chlorobutyl elastomer closure and aluminium or flip off caps.
Type II glass vials of 50 or 100 ml with chlorobutyl elastomer closure and aluminium or flip off caps.
Translucent plastic (HDPE) vials of 15, 60 or 120 ml with chlorobutyl elastomer closure and aluminium or flip off caps.

Plastic box of 2, 10 or 20 glass vials of 2 ml
Cardboard box of 1 glass vial of 10 ml,
Cardboard box of 1 plastic vial of 10 ml
Plastic box of 5 or 10 glass vials of 10 ml
Plastic box of 5 or 10 plastic vials of 10 ml
Cardboard box of 1, 12 or 24 glass vials of 50 ml
Cardboard box of 1, 12 or 24 plastic vials of 50 ml
Cardboard box of 1 glass vial of 100 ml
Cardboard box of 1 plastic vial of 100 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBERS

VPA10454/080/001

8. DATE OF FIRST AUTHORISATION

19/08/2022

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

27/10/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).