ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic box of 2, 10 or 20 vials of 1 dose (2 ml)
Cardboard box of 1 vial of 5 doses (10 ml)
Plastic box of 5 or 10 vials of 5 doses (10 ml)
Cardboard box of 1, 12 or 24 vials of 25 doses (50 ml)
Cardboard box of 1 vial of 50 doses (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fencovis suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per 1 d. (2 ml):
Inactivated *E. coli* expressing F5 (K99) adhesin, strain O8:K35 RP* ≥ 1
Inactivated bovine rotavirus, serotype G6P1, strain TM-91 RP* ≥ 1
Inactivated bovine coronavirus, strain C-197 RP* ≥ 1
*Relative potency

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

2 x 1 dose (2 ml)
10 x 1 dose (2 ml)
20 x 1 dose (2 ml)
1 x 5 doses (10 ml)
5 x 5 doses (10 ml)
10 x 5 doses (10 ml)
1 x 25 doses (50 ml)
12 x 25 doses (50 ml)
24 x 25 doses (50 ml)
1 x 50 doses (100 ml)

5. TARGET SPECIES

Cattle (pregnant heifers and cows).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): 0 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {day/month/year} / {month/year}
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 04491/3000

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml vial (50 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fencovis suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per 1 d. (2 ml):
Inactivated *E. coli* expressing F5 (K99) adhesin, strain O8:K35 RP* ≥ 1
Inactivated bovine rotavirus, serotype G6P1, strain TM-91 RP* ≥ 1
Inactivated bovine coronavirus, strain C-197 RP* ≥ 1
*Relative potency

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

50 doses (100 ml)

5. TARGET SPECIES

Cattle (pregnant heifers and cows).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): 0 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {day/month/year} / {month/year}
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 04491/3000

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 1 dose (2ml), 5 doses (10 ml) and 25 doses (50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fencovis

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1
5
25

2 ml
10 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP: {day/month/year} / {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Fencovis suspension for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturer responsible for batch release:
Bioveta, a. s.,
Komenského 212/12,
683 23 Ivanovice na Hané,
CZECH REPUBLIC

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fencovis suspension for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 2 ml dose contains:

Active substance<s>:

Inactivated *E. coli* expressing F5 (K99) adhesin, strain O8:K35	RP ≥ 1*
Inactivated bovine rotavirus, serotype G6P1, strain TM-91	RP ≥ 1*
Inactivated bovine coronavirus, strain C-197	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 the target animals.

Adjuvants:

Aluminium hydroxide	6 mg
Quillaja saponin (Quil A)	≤ 0.4 mg

Excipients:

Thiomersal	0.2 mg
Formaldehyde	≤ 1 mg

Appearance: orange, pink to deep pink liquid with whitish sediment, which is homogenously dispersed after shaking.

4. INDICATION(S)

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 cows for the first week of life, the laboratory studies conducted with heterologous challenges 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 heifers or cows, 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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

An increase in mean body temperature of 1.0°C was very commonly observed in laboratory and field studies; in individual cases the maximum increase may reach 2.1°C, with body temperatures resolving to normal levels within 2 days without impairing the general health status of the vaccinated animals.
A localised mild swelling (≤ 5 cm in diameter) at the injection site resolving within 2 days was commonly observed in field studies.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1.000 animals treated)
- rare (more than 1 but less than 10 animals in 10.000 animals treated)
- very rare (less than 1 animal in 10.000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle (pregnant heifers and cows)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 calf 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.

9. ADVICE ON CORRECT ADMINISTRATION

Once open, the vials should not be stored above 25°C.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 10 hours

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Special precautions for use in animals:
To achieve optimum results and to reduce infection pressure on the farm, a whole herd cow 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.

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

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.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Not all pack sizes may be marketed.

Package size:
Plastic box of 2, 10 or 20 glass vials of 1 dose (2 ml)
Cardboard box of 1 glass or plastic vial of 5 doses (10 ml)
Plastic box of 5 or 10 glass or plastic vials of 5 doses (10 ml)
Cardboard box of 1, 12 or 24 glass or plastic vials of 25 doses (50 ml)
Cardboard box of 1 glass or plastic vial of 50 doses (100 ml)

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 27 July 2022