

**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 (AT, BE, CZ, DE, EL, ES, FR, IE, IT, LU, NL, PT, UK(NI))  
Fencovis RCE vet suspension for injection (FI, NO, SE)

### **2. STATEMENT OF ACTIVE SUBSTANCES**

Per 1 d. (2 ml):

Inactivated *E. coli* expressing F5 (K99) adhesin, strain O8:K35 RP\*  $\geq$  1

Inactivated bovine rotavirus, serotype G6P1, strain TM-91 RP\*  $\geq$  1

Inactivated bovine coronavirus, strain C-197 RP\*  $\geq$  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  
55216 Ingelheim/Rhein  
GERMANY

**16. MARKETING AUTHORISATION NUMBER(S)**

To be completed locally

**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 (AT, BE, CZ, DE, EL, ES, FR, IE, IT, LU, NL, PT, UK(NI))  
Fencovis RCE vet suspension for injection (FI, NO, SE)

**2. STATEMENT OF ACTIVE SUBSTANCES**

Per 1 d. (2 ml):

Inactivated *E. coli* expressing F5 (K99) adhesin, strain O8:K35 RP\*  $\geq 1$

Inactivated bovine rotavirus, serotype G6P1, strain TM-91 RP\*  $\geq 1$

Inactivated bovine coronavirus, strain C-197 RP\*  $\geq 1$

\*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  
55216 Ingelheim/Rhein  
GERMANY

**16. MARKETING AUTHORISATION NUMBER(S)**

*To be completed locally*

**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 (AT, BE, CZ, DE, EL, ES, FR, IE, IT, LU, NL, PT, UK(NI))  
Fencovis RCE vet (FI, NO, SE)

**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.