

**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

<b>16. MARKETING AUTHORISATION NUMBER(S)</b>
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To be completed locally

<b>17. MANUFACTURER'S BATCH NUMBER</b>
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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**

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**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.