

*I*

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

{Cartonboard box}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Flortekxin 300 mg/ml + 16.5 mg/ml solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substances:**

Florfenicol 300.0 mg

Flunixin 16.5 mg

(as flunixin meglumine)

**3. PACKAGE SIZE**

100 ml

250 ml

**4. TARGET SPECIES**

Cattle

**5. INDICATIONS****6. ROUTES OF ADMINISTRATION**

Subcutaneous use.

**7. WITHDRAWAL PERIODS**

Withdrawal period:

Meat and offal: 46 days.

Milk: Not authorised for use in animals producing milk for human consumption.

Do not use in pregnant animals which are intended to produce milk for human consumption within 2 months of expected parturition.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days

Once broached use by...

|                                       |
|---------------------------------------|
| <b>9. SPECIAL STORAGE PRECAUTIONS</b> |
|---------------------------------------|

Do not store above 30 °C

|  |
|--|
| <b>10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”</b> |
|--|

Read the package leaflet before use.

|  |
|--|
| <b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b> |
|--|

For animal treatment only.

|  |
|--|
| <b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b> |
|--|

Keep out of the sight and reach of children.

|   |
|---|
| <b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b> |
|---|

{logo name of the marketing authorisation holder}

|  |
|--|
| <b>14. MARKETING AUTHORISATION NUMBERS</b> |
|--|

|                         |
|-------------------------|
| <b>15. BATCH NUMBER</b> |
|-------------------------|

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

{Vial 100ml, 250ml}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Flortekxin 300 mg/ml + 16.5 mg/ml solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substances:**

Florfenicol 300.0 mg

Flunixin 16.5 mg

(as flunixin meglumine)

**3. TARGET SPECIES**

Cattle

**4. ROUTES OF ADMINISTRATION**

Subcutaneous use.

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal period:

Meat and offal: 46 days.

Milk: Not authorised for use in animals producing milk for human consumption.

Do not use in pregnant animals which are intended to produce milk for human consumption within 2 months of expected parturition.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days

Once broached use by...

**7. SPECIAL STORAGE PRECAUTIONS**

Do not store above 30 °C.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

{logo name of the marketing authorisation holder}

|                        |
|------------------------|
| <b>9. BATCH NUMBER</b> |
|------------------------|

Lot {number}