A. LABELLING

# PARTICULARS TO APPEAR ON THE OUTER PACKAGE

#### CARTON BOX 100 ml and 250 ml

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

Cadorex 300 mg/ml solution for injection for cattle, sheep and pigs [AT, BG, CY, CZ, DE, EE, EL, FR, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK]

Flodoex 300 mg/ml solution for injection for cattle, sheep and pigs [BE]

Cadorex vet, 300 mg/ml solution for injection for cattle, sheep and pigs [DK]

Cadorex vet 300 mg/ml solution for injection [FI]

Florfenicol

# 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Florfenicol... 300 mg

#### 3. PHARMACEUTICAL FORM

Solution for injection.

#### 4. PACKAGE SIZE

100 ml 250 ml

#### 5. TARGET SPECIES

Cattle, sheep and pigs.

#### 6. INDICATION(S)

Read the package leaflet before use.

# 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Intramuscular or subcutaneous use

Sheep: Intramuscular use Pigs: Intramuscular use

Read the package leaflet before use.

# 8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle:

Meat and offal: by IM route: 30 days

by SC route: 44 days

Milk: Not authorised for use in lactating animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

Sheep:

Meat and offal: by IM route: 39 days

Milk: Not authorised for use in lactating animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

Pigs:

Meat and offal: by IM route: 18 days

# 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

#### 10. EXPIRY DATE

EXP [month/year]

Once opened, use within 28 days.

Once broached, use by ...

# 11. SPECIAL STORAGE CONDITIONS

Store below 30°C.

Do not freeze.

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

Dispose of waste material in accordance with local requirements.

# 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

LIVISTO Int'l, S.L.

Av. Universitat Autònoma, 29 08290 Cerdanyola del Vallès

Danaslana (Carain)

Barcelona (Spain)

# 16. MARKETING AUTHORISATION NUMBER(S)

# 17. MANUFACTURER'S BATCH NUMBER

Batch:

# PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

#### LABEL 100 ml and 250 ml

# 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cadorex 300 mg/ml solution for injection for cattle, sheep and pigs [AT, BG, CY, CZ, DE, EE,

EL, FR, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK]

Flodoex 300 mg/ml solution for injection for cattle, sheep and pigs [BE]

Cadorex vet, 300 mg/ml solution for injection for cattle, sheep and pigs [DK]

Cadorex vet 300 mg/ml solution for injection [FI]

Florfenicol

# 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Florfenicol..... 300 mg

#### 3. PHARMACEUTICAL FORM

Solution for injection.

#### 4. PACKAGE SIZE

100 ml

250 ml

# 5. TARGET SPECIES

Cattle, sheep and pigs.

# 6. INDICATION(S)

# 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Intramuscular or subcutaneous use

Sheep: Intramuscular use Pigs: Intramuscular use

Read the package leaflet before use.

# 8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle:

Meat and offal: by IM route: 30 days

by SC route: 44 days

Milk: Not authorised for use in lactating animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

Sheep:

Meat and offal:	by IM route:	39 days
Micai and Onai.	by hyr route.	J) uavs

Milk: Not authorised for use in lactating animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

Pigs:

Meat and offal: by IM route: 18 days

# 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

### 10. EXPIRY DATE

EXP [month/year]

Once opened, use within 28 days.

Once broached, use by ...

# 11. SPECIAL STORAGE CONDITIONS

Store below 30°C.

Do not freeze.

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

Dispose of waste material in accordance with local requirements.

# 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

LIVISTO Int'l, S.L.

Av. Universitat Autònoma, 29 08290 Cerdanyola del Vallès Barcelona (Spain)

# 16. MARKETING AUTHORISATION NUMBER(S)

#### 17. MANUFACTURER'S BATCH NUMBER

Batch: