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 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:	
	by SC route:	

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

Sheep:

30 days 44 days Meat and offal: by IM route: 39 days

by IM route:

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:

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: