A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box with 1 vial of 100 ml

Carton box with 1 vial of 250 ml

Carton box with 10 vials of 100 ml

Carton box with 15 vials of 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PULMOVALL 300 mg/ml solution for injection for cattle, sheep and pigs Florfenicol

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance

Florfenicol......300 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 vial of 100 ml

1 vial of 250 ml

10 vials of 100 ml

15 vials of 250 ml

5. TARGET SPECIES

Cattle, sheep and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular and subcutaneous use in cattle. For intramuscular use in sheep and pig. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:

Meat and offal

Cattle: IM use (20 mg/kg bodyweight, twice): 30 days.

SC use (40 mg/kg bodyweight, once): 44 days.

Sheep: 39 days.

Pig: 18 days.

Milk

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

This product may be harmful for the unborn child.

10. EXPIRY DATE

EXP {month/year}

Once opened use by:

Shelf life after first opening the container: 28 days.

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

This veterinary medicinal product is dangerous for aquatic organisms (such as cyanobacteria). Do not contaminate surface waters or ponds with used product or containers.

Disposal: read 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. Administration by a veterinary surgeon or under their direct responsibility.

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

MEVET S.A.U. Polígono Industrial El Segre, parcela 409-410, 25191 Lleida SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

1	_		ATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE Vial of 100 ml Vial of 250 ml 1. NAME OF THE VETERINARY MEDICINAL PRODUCT PULMOVALL 300 mg/ml solution for injection for cattle, sheep and pigs Florfenicol 2. STATEMENT OF ACTIVE SUBSTANCES Each ml contains: **Active substance** 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 For intramuscular and subcutaneous use in cattle. For intramuscular use in sheep and pig. Read the package leaflet before use. 8. WITHDRAWAL PERIOD(S) Meat and offal Cattle: IM use (20 mg/kg bodyweight, twice): 30 days. SC use (40 mg/kg bodyweight, once): 44 days.

Milk

Sheep:

Pig:

39 days.

18 days.

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

This product may be harmful for the unborn child.

10. EXPIRY DATE

EXP {month/year}

Once opened use by:

Shelf life after first opening the container: 28 days.

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to 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. Administration by a veterinary surgeon or under their direct responsibility.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MEVET S.A.U. Polígono Industrial El Segre, p. 409-410, 25191 Lleida SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}