

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 6 vials of 100 ml

Carton box with 6 vials of 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BE, DE, DK, EL, FR, HU, IE, LT, NL, PL, PT, RO: FLORFENIS 300 mg/ml solution for injection

IT: SYVAFLO 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Florfenicol.....300 mg/ml

3. PACKAGE SIZE

100 ml

250 ml

6 x 100 ml

6 x 250 ml

4. TARGET SPECIES

Cattle, sheep and pigs

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

For intramuscular and subcutaneous use in cattle.

For intramuscular use in sheep and pigs.

7. WITHDRAWAL PERIODS

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.

Pigs: 18 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.

8. EXPIRY DATE

Exp {mm/yyyy}

Once opened use by:

Once opened use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Syva S.A.

14. MARKETING AUTHORISATION NUMBERS**15. BATCH NUMBER**

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 100 ml

Vial of 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BE, DE, DK, EL, FR, HU, IE, LT, NL, PL, PT, RO: FLORFENIS 300 mg/ml solution for injection

IT: SYVAFLO 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Florfenicol.....300 mg/ml

3. TARGET SPECIES

Cattle, sheep and pigs

4. ROUTES OF ADMINISTRATION

For intramuscular and subcutaneous use in cattle.

For intramuscular use in sheep and pigs.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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.

Pigs: 18 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.

6. EXPIRY DATE

Exp {mm/yyyy}

Once opened use by:

Once opened use within: 28 days.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER
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Laboratorios Syva S.A.

9. BATCH NUMBER

Lot {number}