# B. PACKAGE LEAFLET

**PACKAGE LEAFLET:**

## 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 for cattle, sheep and pigs

[IT]: SYVAFLOR 300 mg/ml solution for injection for cattle, sheep and pigs

## 2. Composition

Each ml contains:

**Active substance:**
Florfenicol……..300 mg

**Excipient(s):**
N-methyl pyrrolidone…….250 mg

Clear, yellowish solution, free from visible particles in suspension.

## 3. Target species

Cattle, sheep and pigs.

## 4. Indications for use

Cattle: Treatment and metaphylaxis of bovine respiratory disease associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* susceptible to florfenicol. The presence of the disease in the group must be established before metaphylactic treatment.

Sheep**:** Treatment of ovine respiratory disease associated with *Mannheimia haemolytica* and *Pasteurella multocida* susceptible to florfenicol.

Pigs: Treatment of acute outbreaks of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol.

## 5. Contraindications

Do not use in adult bulls, rams and boars intended for breeding purposes.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

## 6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
Do not use in piglets of less than 2 kg.

The safety of the veterinary medicinal product has not been established in sheep younger than 7 weeks of age.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Official, national and regional antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol and may decrease the effectiveness of treatment with amphenicols due to potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The product can cause hypersensitivity (allergy). People with known hypersensitivity to florfenicol, propylene glycol o to polyethylene glycols should avoid contact with the veterinary medicinal product.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

Administer the veterinary medicinal product with caution to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. This product may cause skin and eye irritation. Avoid contact with skin or eyes. In case of accidental contact, wash immediately exposed area with plenty of clean water.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the physician the package leaflet or the label.

Special precautions for the protection of the environment:
The use of this veterinary medicinal product may pose a risk for terrestrial plants, cyanobacteria and groundwater organisms.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in cattle, sheep and pigs during pregnancy, lactation, or in animals intended for breeding. Studies in laboratory animals have not revealed any evidence of embryo- or foetotoxic potential for florfenicol. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:
Do not use in adult bulls, rams and boars intended for breeding (see section 5).

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:

Cattle:
No symptoms other than those described in *Adverse events*.

Sheep:
After administration of 3 times the recommended dose or more, a transient reduction in feed and water consumption has been observed. Additional effects included an increased incidence of lethargy, emaciation and loose faeces.

Head tilt was seen after administration of 5 times the recommended dose and was considered most likely a result of irritation at the injection site.

Pigs:
After administration of 3 times the recommended dose or more a reduction in feeding, water consumption and weight gain has been observed.
After administration of 5 times the recommended dose or more vomiting has also been noted.

Special restrictions for use and special conditions for use:

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## 7. Adverse events

Cattle:

| Very rare (<1 animal / 10,000 animals treated, including isolated reports) |
|---|
| Anaphylactic shock (severe allergic reaction)<br>Reduced food intake[1]<br>Loose stool[1,2]<br>Injection site inflammation[3] |

[1] Treated animals recover quickly and completely upon termination of treatment.
[2] Transient.
[3] After intramuscular and subcutaneous administration. May persist for 14 days.

Sheep:

| Very rare (<1 animal / 10,000 animals treated, including isolated reports) |
|---|
| Reduced food intake[1]<br>Injection site inflammation[2] |

[1] The treated animals recover quickly and completely upon termination of treatment.
[2] After intramuscular administration. Inflammation may persist up to 28 days. Typically, these are mild and transient.

Pigs:

| Very common (>1 animal / 10 animals treated) |
|---|
| Diarrhoea[1]<br>Anal and Rectal oedema (swelling)[1]<br>Erythema (redness)[1, 2]<br>Pyrexia (fever), Depression[3]<br>Dyspnoea (difficulty breathing)[3] |
| Very rare (<1 animal / 10,000 animals treated, including isolated reports) |
| Injection site swellling[4], Injection site inflammation[5] |

[1] These effects are transient and can be observed for one week.
[2] Peri-anal and rectal erythema.
[3] Pyrexia (40ºC) associated with either moderate depression or moderate dyspnoea a week or more after administration of the second dose.
[4] Transient swelling lasting up to 5 days.
[5] Inflammatory lesions may be seen up to 28 days.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in first instance, your veterinarian. You can also report any adverse event to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

## 8. Dosage of each species, routes and method of administration

**Administration route**:
For intramuscular and subcutaneous use in cattle.
For intramuscular use in sheep and pigs.

**For treatment:**
Cattle**:**
Intramuscular use: 20 mg florfenicol/kg bodyweight (equivalent to 1 ml of the veterinary medicinal product/15 kg bodyweight) to be administered twice 48 hours apart.
Subcutaneous use: 40 mg florfenicol/kg bodyweight (equivalent to 2 ml of the veterinary medicinal product/15 kg bodyweight) to be administered once only
For both routes: use a 16-gauge needle. The dose volume given at any one injection site should not exceed 10 ml. The injection should only be given in the neck.

Sheep:
Intramuscular use: 20 mg florfenicol/kg bodyweight (equivalent to 1 ml of the veterinary medicinal product/15 kg bodyweight) to be administered daily for three consecutive days.
The volume administered per injection site should not exceed 4 ml.

Pigs:
Intramuscular use: 15 mg florfenicol/kg bodyweight (equivalent to 1 ml of the veterinary medicinal product/20 kg bodyweight) by intramuscular injection into the neck muscle twice at 48-hour intervals using a 16-gauge needle.
The volume administered per injection site should not exceed 3 ml.
It is recommended to treat animals in the early stages of the disease and to evaluate the response to treatment within 48 hours after the last injection. If clinical signs of respiratory disease persist or increase within, or if relapse occurs, treatment should be changed, using another antibiotic, and continued until clinical signs have resolved.

**For metaphylaxis**
Cattle:
Subcutaneous use: 40 mg florfenicol/kg bodyweight (equivalent to 2 ml of the veterinary medicinal product/15 kg bodyweight) to be administered once only using a 16-gauge needle. The dose volume given at any one injection site should not exceed 10 ml.
The injection should only be given in the neck.

**For all target species:** To ensure a correct dosage, body weight should be determined as accurately as possible.

## 9. Advice on correct administration

The closure must not be punctured more than 50 times.
When treating groups of animals at the same time, use of a draw-off needle in the vial stopper is recommended to avoid excess stopper broaching. The draw-off needle should be removed after treatment.

## 10. Withdrawal periods

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.

## 11. Special storage precautions

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

The veterinary medicinal product should not enter water courses as florfenicol may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your <veterinary surgeon> or <pharmacist> how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack size

Pack sizes:
Cardboard box with 1 vial of 100 ml
Cardboard box with 1 vial of 250 ml
Cardboard box with 6 vials of 100 ml
Cardboard box with 6 vials of 250 ml

Not all pack sizes may be marketed.

## 15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder:
Laboratorios Syva S.A.
Calle Marqués de la Ensenada, 16
28004 MADRID
SPAIN

Manufacturer responsible for batch release:
Laboratorios Syva S.A.
Avenida del Párroco Pablo Díez, 49-57
San Andrés del Rabanedo
24010 LEÓN
SPAIN

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

## 17. Other information