PACKAGE LEAFLET

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 (NI)]
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]

2. Composition

Each ml contains:

Active substance:
Florfenicol…… 300 mg
Excipients:
N-Methylpyrrolidone 250 mg

Clear, light yellow to straw-coloured, somewhat viscous solution, free from foreign matter.

3. Target species

Cattle, sheep and pigs.

4. Indications for use

Cattle:
Diseases caused by florfenicol susceptible to bacteria: Metaphylactic and therapeutic treatment of respiratory tract infections in cattle due to *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni.* The presence of the disease in the group must be established before the veterinary medicinal product is used.

Sheep:
Treatment of ovine respiratory tract infections due to *Mannheimia haemolytica* and *Pasteurella multocida*.

Pigs:
Treatment of acute outbreaks of swine respiratory disease caused by strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

5. Contraindications

Do not use in adult bulls and rams intended for breeding purposes.
Do not administer to boars intended for breeding.
Do not use in case of known 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:
This veterinary medicinal product does not contain any antimicrobial preservative.

The safety of the veterinary medicinal product has not been established in sheep under 7 weeks of age.
Do not use in piglets of less than 2 kg.
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogens. Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the florfenicol and may decrease the effectiveness of treatment with amphenicols due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause hypersensitivity (allergy).
People with known hypersensitivity to florfenicol, propylene glycol or 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.
Take care 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.
Avoid skin or eye contact with the veterinary medicinal product. In case of contact with the skin or eyes, rinse the affected area immediately with plenty of clean water.
If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the physician the package leaflet or the label.
Wash hands after use.

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 section 7.
Sheep:
After administration of 3 times the recommended dose or more, a transient reduction in feed and water consumption has been observed. Additional secondary effects that were noted 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.
Swine:

After administration of 3 times the recommended dose or more, a reduction in feeding, hydration 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:
Not applicable.

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):	Reduced food intake[1] Loose stool[1] Injection site inflammation[2] Anaphylactic (severe allergic reaction) shock

[1] The treated animals recover quickly and completely upon termination of treatment.
[2] It may persist for 14 days.

Sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Reduced food intake[3] Injection site inflammation[4]

[3] The treated animals recover quickly and completely upon termination of the treatment.
[4] It may persist up to 28 days. Typically, these are mild and transient.

Pigs:

Very common (>1 animal / 10 animals treated):	Pyrexia (elevated temperature) [5,6] Respiratory depression[7], dyspnoea[7] Diarrhoea[8], anal and rectal disorder (erythema/oedema)[8]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[9], injection site inflammation[10]

[5] 40ºC
[6] These effects were observed in approximately 30% of treated pigs associated with either moderate depression or moderate dyspnoea a week or more after administration of the second dose.
[7] Moderate
[8] These effects, may affect 50% of the animals. These effects can be observed for one week (transient).
[9] It may be observed up to 5 days.
[10] It 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 the first instance, your veterinarian. You can also report any adverse events 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 for each species, routes and method of administration

For intramuscular and subcutaneous use in cattle.
For intramuscular use in sheep and pigs.

For treatment
Cattle:
Intramuscular route: 20 mg of florfenicol/kg bodyweight (equivalent to 1 ml of the veterinary medicinal product/15 kg bodyweight) to be administered twice 48 hours apart using a 16 gauge needle.
Subcutaneous route: 40 mg of florfenicol/kg bodyweight (equivalent to 2 ml of the veterinary medicinal product/15 kg bodyweight) to be administered once 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.

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

Pigs:
15 mg of 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 hours intervals using a 16-gauge needle.
The volume administered per injection site should not exceed 3 ml.
For intramuscular, it is recommended to treat animals in the early stages of disease and to evaluate the response to treatment within 48 hours after the second injection. If clinical signs of respiratory disease persist 48 hours after the last injection, treatment should be changed using another formulation or 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.

9. Advice on correct administration

Wipe the stopper before removing each dose. Use a dry sterile needle and syringe.
To ensure a correct dosage, body weight should be determined as accurately as possible.
As the vial should not be broached more than 25 times, the user should select the most appropriate vial size according to the target species to be treated. When treating groups of animals in one run, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle should be removed after treatment.

10. Withdrawal period

Cattle:

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

Milk: Not authorized for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption.

Sheep:
Meat and offal: by IM route: 39 days

Milk: Not authorized for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption.

Pigs:
Meat and offal: by IM route: 18 days

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 30ºC.
Do not freeze.

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 sizes

Package sizes:
Cardboard box containing 1 vial of 100 ml
Cardboard box containing 1 vial of 250 ml
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{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 and manufacturer responsible for batch release:
Industrial Veterinaria, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat
(Barcelona) Spain

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

<Local representatives <and contact details to report suspected adverse reactions>:>
To be completed nationally