B. PACKAGE LEAFLET

PACKAGE LEAFLET:
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]

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès
Barcelona (Spain)

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

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

2. 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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:
Florfenicol…… 300 mg
Excipients, q.s.
Clear, light yellow to straw-coloured, somewhat viscous solution, free from foreign matter.

4. INDICATION(S)

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 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. ADVERSE REACTIONS

Cattle:
A decrease in food consumption and transient softening of the faeces may occur very rare during the treatment period. The treated animals recover quickly and completely upon termination of treatment.
Administration of the product by the intramuscular and subcutaneous routes may cause inflammatory lesions at injection site very rare which persist for 14 days.
Anaphylactic shocks have been reported in bovines in very rare cases.

Sheep:
A decrease in food consumption may occur very rare during the treatment period. The treated animals recover quickly and completely upon termination of the treatment.
Administration of the product by the intramuscular route may cause inflammatory lesions at the injection site very rare which may persist up to 28 days. Typically, these are mild and transient.

Pigs:
Commonly observed adverse effects are transient diarrhoea and/or peri-anal and rectal erythema/oedema which may affect 50% of the animals. These effects can be observed for one week.
Under field conditions approximately 30% of treated pigs presented with pyrexia (40ºC) associated with either moderate depression or moderate dyspnoea a week or more after administration of the second dose.
Transient swelling lasting up to 5 days may be observed at the site of injection very rare. Inflammatory lesions at the injection site may be seen up to 28 days.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, sheep and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 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 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 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 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 to avoid underdosing.
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 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

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 container: 28 days

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals:
This medicinal product does not contain any antimicrobial preservative.
The safety of the 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 product should be based on identification and susceptibility testing of the target pathogens. Use of the product should be in accordance with official, national and regional antimicrobial policies.
Use of the 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 other amphenicols due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product may cause hypersensitivity (allergy).
People with known hypersensitivity to florfenicol, propylene glycol or polyethylene glycols should avoid contact with the veterinary medicinal product.
This product contains N-Methylpyrrolidone which may be harmful for the unborn child; therefore, women of child-bearing age must be very careful to avoid exposure via spillage onto the skin or accidental self-injection when administering the product. If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the product.
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 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.

Other precautions:
Florfenicol is toxic for terrestrial plants, cyanobacteria and groundwater organisms.

Pregnancy and lactation:
Studies in laboratory animals have not revealed any evidence of embryo- or foetotoxic potential for florfenicol. Laboratory studies with the excipient N-methylpyrrolidone in rabbits and rats have shown evidence of teratogenic, foetotoxic, maternotoxic and reprotoxic effects.
Cattle and Sheep
The effect of florfenicol on bovine and ovine reproductive performance and pregnancy has not been assessed. Do not use the product during pregnancy and lactation.
Pigs
The safety of the product in sows during pregnancy and lactation has not been demonstrated.
Do not use the product during pregnancy and lactation.

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

Overdose (symptoms, emergency procedures, antidotes):
Cattle:
No symptoms other than those described in section 6..
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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD month YY

15. OTHER INFORMATION

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.