PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

HDPE container 1 L and 5 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cadorex 100 mg/ml solution for use in drinking water for pigs and chickens

2. COMPOSITION

Each ml contains:

Active substance:
Florfenicol 100 mg

Clear, colourless to yellowish solution

3. PACKAGE SIZE

1 L
5 L

4. TARGET SPECIES

Pig, chicken

5. INDICATIONS FOR USE

Indications for use

Pig:

Treatment and metaphylaxis of respiratory infections caused by florfenicol susceptible bacteria such as: Pleuropneumonia (*Actinobacillus pleuropneumoniae*), atrophic rhinitis (*Pasteurella multocida, Bordetella bronchiseptica*), *Glasserella parasuis* infections, enzootic bronchopneumonia (*Mycoplasma hyopneumoniae*) and *Streptococcus suis* infections.
The presence of the disease in the group must be established before the product is used.

Chicken:

Treatment of infections caused by florfenicol susceptible bacteria such as: *Staphylococcus* spp., *E. coli*, *Ornithobacterium rhinotracheale, Pasteurella* spp.; acute catarrh conditions of the upper respiratory tract and other diseases caused by pathogens susceptible to florfenicol.

6. CONTRAINDICATIONS

Contraindications
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
The oral uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead, using a suitable injectable product prescribed by the veterinarian.

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause irritation to skin and eyes. Personal protective equipment consisting of appropriate clothes, gloves, goggles, and mask should be worn when handling the veterinary medicinal product.
In case of accidental contact with skin or eyes, rinse these areas with plenty of water, if symptoms persist seek medical advice immediately and show the package leaflet or the label to the physician.

This veterinary medicinal product may be harmful when ingested, including effects on male fertility. Avoid oral ingestion, including hand-to-mouth contact when preparing the veterinary medicinal product. Do not smoke, eat or drink while handling the veterinary medicinal product. In the case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to florfenicol or to the excipient should avoid contact with the veterinary medicinal product. If you develop symptoms following exposure, such as skin rush, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.
Wash hands after use.

Special precautions for the protection of the environment:
Manure from treated animals may be harmful to cyanobacteria and terrestrial plants.

Pregnancy and lactation:
Laboratory studies in rats and mice have shown evidence of teratogenic and maternotoxic effects.
The safety of the veterinary medicinal product in sows has not been established during pregnancy and lactation. The use is not recommended during those periods of time.

Fertility:
Do not administer to boars intended for breeding.

Laying birds:
Do not use in birds in lay.

Interactions with other medicinal products and other forms of interaction:
Do not use simultaneously with thiamphenicol.

Overdose:
In case of overdosing, a decrease in bodyweight gain, food and water consumption, peri-anal erythema and oedema may be observed. Due to dehydration, some haematological and biochemical parameters can be modified.
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.
Data and information are available which show that this veterinary medicinal product can be used simultaneously and/or dissolved in drinking water with active chlorine or hydrogen peroxide.
This veterinary medicinal product may be administered using drinking water containing active chlorine at a maximum concentration of 1 ppm and hydrogen peroxide at a maximum concentration of 35 ppm.

8. ADVERSE EVENTS

Adverse events

Pig:

Undetermined frequency (cannot be estimated from the available data):	Anal irritation (erythema), anal oedema Diarrhoea, constipation, unusual stool colour[1)] Decreased drinking

1) Faeces turn a dark brown colour.

Chicken: None known.

Reporting adverse events is important. It allows continuous safety monitoring of a the veterinary medicinal product. If you notice any side effects, even those not already listed on this label, 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 on this label, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Pig:
The daily dose is 10 mg florfenicol per kg body weight (0,1 ml of the veterinary medicinal product per kg body weight). Treatment should be continued for 5 days.

Chicken:
The daily dose is 20 mg florfenicol per kg body weight (0,2 ml of the veterinary medicinal product per kg body weight).
Treatment should be continued for 3-5 days.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{ml veterinary medicinal product / kg body weight/ day} \times \text{Average body weight (kg) of animals to be treated}}{\text{Average daily water intake (l/animal)}} = \text{ml veterinary medicinal product per litre of drinking water}$$

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of florfenicol may need to be adjusted accordingly.

The appropriate quantity of medicated water or pre-diluted medicated water should be prepared based on the daily water consumption.

The product should first be diluted in water to obtain a stock solution to be diluted in the drinking water tank or introduced by means of a water dosing pump.

When using a proportioner, adjust flow rate setting of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.
Solution with concentration of the veterinary medicinal product equal or higher than 12 ml/ liter may precipitate.

Medicated drinking water should be refreshed or replaced every 24 hours.

11. WITHDRAWAL PERIODS

Withdrawal periods

Pig: Meat and offal: 20 days.

Chicken: Meat and offal: 8 days.
Not for use in birds producing or intended to produce eggs for human consumption.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Store below 30°C.

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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

This 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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes
1 l bottle
5 l bottle

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:

Industrial Veterinaria, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat (Barcelona), Spain
+34 93 470 62 70

Manufacturer responsible for batch release:

Industria Italiana Integratori TREI S.p.A.
Via Affarosa 4, 42010
Rio Saliceto (RE)

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell

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

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

18. OTHER INFORMATION

Other information

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution according to directions: 24 hours.

21. BATCH NUMBER

Lot {number}