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ANNEX III
LABELLING AND PACKAGE LEAFLET

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Flortekxin 300 mg/ml + 16.5 mg/ml solution for injection for cattle

2. Composition

Each ml contains:

Active substances:

Florfenicol 300.0 mg

Flunixin 16.5 mg

(as flunixin meglumine)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Propylene glycol (E1520)	150.0 mg
N-methylpyrrolidone	250.0 mg

Clear, yellow, free from visible particles solution for injection.

3. Target species

Cattle

4. Indications for use

Treatment of respiratory infections caused by *Histophilus somni*, *Mannheimia haemolytica*, *Pasteurella multocida* and *Mycoplasma bovis*, associated with pyrexia.

5. Contraindications

Do not use in adult bulls intended for breeding purposes.

Do not use in animals suffering from hepatic and renal diseases.

Do not use if there is a risk of gastrointestinal bleeding or in cases where there is evidence of altered hemostasis.

Do not use in animals suffering from cardiac diseases.

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

6. Special warnings

Cross-resistance has been shown between florfenicol and chloramphenicol. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to florfenicol and other amphenicols because its effectiveness may be reduced.”

Despite a reduction in *Mycoplasma bovis* pathogen load, *Mycoplasma bovis* may not be fully eliminated from the lungs after treatment with the veterinary medicinal product.
There is no bacterial eradication of *Mycoplasma bovis*.

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). 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. Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol.

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.

Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

Concurrent administration of potentially nephrotoxic drugs should be avoided.

Repeated daily dosing has been associated with abomasal erosions in the pre-ruminant calf. The veterinary medicinal product should be used with caution in this age group.

The safety of the veterinary medicinal product has not been tested in calves of 3 weeks of age or less.

Not for use for prophylaxis or metaphylaxis.

Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Care should be taken 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 hypersensitivity. People with known hypersensitivity to propylene glycol and 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.

Wash hands after use.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established in cattle during pregnancy, lactation, or in animals intended for breeding. 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 intended for breeding (see section 5)

Interaction with other medicinal products and other forms of interaction:

Concurrent use of other active substances that have a high degree of protein binding may compete with flunixin for binding and thus lead to toxic effects. Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before the commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the veterinary medicinal products used previously. The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given NSAIDs.

Overdose:

Overdose studies in the target species for 3 times the duration of treatment showed decreased food consumption in the groups given 3 and 5 times the recommended dose. Decreased body weights were observed in the 5 times overdose group (secondary to decreased food consumption). Decreased water consumption was observed in the 5 times overdose group. Tissue irritation increases with injection volume. Treatment at 3 times the recommended treatment duration was associated with dose-related erosive and ulcerative abomasum lesions.

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 reactions (sometimes fatal)
Undetermined frequency (cannot be estimated from the available data)	Injection site swelling ¹ , injection site irritation ²

¹Become palpable 2-3 days after injection. The duration ranged from 15-36 days post-injection.

²Minimal to mild irritation of the subcutis. Extension into the underlying muscle was note only a few instances. By 56 days post-dosing, no gross lesions were observed that would require any trim-out at slaughter.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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

Subcutaneous use.

40 mg/kg florfenicol and 2.2 mg/kg flunixin (2 ml/15 kg body weight) to be administered by a single subcutaneous injection. The dose volume given at any one injection should not exceed 10 ml.

It is recommended to treat animals in the early stages of the disease and to evaluate the response to treatment within the 48 hours after injection. The anti-inflammatory component of the veterinary medicinal product, flunixin, may mask a poor bacteriological response to florfenicol in the first 24 hours after injection. If clinical signs of respiratory disease persists or increases, or if relapse occurs, treatment should be changed, using another antibiotic, and continue until clinical signs have resolved.

The injection should only be given in the neck. Swab septum 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.

For 100 ml vial: The cap may be safely punctured up to 20 times.

For 250 ml vial: The cap may be safely punctured up to 40 times.

9. Advice on correct administration

None.

10. Withdrawal periods

Meat and offal: 46 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 within 2 months of expected parturition.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 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.

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.

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 with 1 vial of 100 ml.

Cardboard box with 1 vial of 250 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder:

Laboratorios Karizoo, S.A.
Pol. Ind. La Borda, Mas Pujades 11-12
08140 Caldes de Montbui (Barcelona)
Spain
Tel. +34 93 865 41 48

Manufacturer responsible for batch release:

Vet-Agro Multi-Trade Company Sp. z o.o.
Mełgiewska 18,
20-234 Lublin, Poland

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

Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.