PRODUCT LABELLING

LABEL-LEAFLET

[ES]
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CN:XXXXXX.X

K-FLOX 100 mg/ml Oral solution for chickens and rabbits [ES, IT, PT, CY]
Enrofloxacin
AMIPLUS 100 mg/ml Oral solution for chickens and rabbits [EL]
Enrofloxacin

1-L bottles
5-L barrels

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

Marketing authorisation holder:
LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
Spain

Manufacturer responsible for batch release:
LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
Spain

SP VETERINARIA SA.
Ctra. Reus-Vinyols Km 4.1.
43330 Riudoms (Tarragona)

Distributed by:

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

K-FLOX 100 mg/ml Oral solution for chickens and rabbits [ES, IT, PT, CY]
Enrofloxacin
AMIPLUS 100 mg/ml Oral solution for chickens and rabbits [EL]
Enrofloxacin

3. STATEMENT OF ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Active substance:
Enrofloxacin..... 10.0 g

Excipients:
Benzyl Alcohol..... 1.4 ml
Excipients to..... 100 ml

Solution for use in drinking water.
An aqueous, clear, yellowish solution.

4. INDICATIONS

Treatment of infections caused by the following bacteria susceptible to enrofloxacin:

CHICKENS
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,
Pasteurella multocida,

RABBITS
Treatment of respiratory infections due to *P.multocida*.

5. CONTRAINDICATIONS

Do not use for prophylaxis.
Do not use when resistance/ cross-resistance to (fluoro)quinolones is known to occur in the flock intended for treatment.
Do not use in case of known hypersensitivity to the active substance, other (fluoro)quinolones or to any of the excipients.

6. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned in this label-leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (broilers) and rabbits

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For oral administration via the drinking water.

CHICKENS
10 mg enrofloxacin/kg bodyweight per day for 3-5 consecutive days (equivalent to 0.1 ml.product/kg b.w. /day).
Treatment for 3-5 consecutive days; for 5 consecutive days in mixed infections and chronic progressive forms. If no clinical improvement is achieved within 2-3 days, alternative antimicrobial therapy should be considered based on susceptibility testing.

RABBITS
10 mg enrofloxacin/kg bodyweight per day for 5 consecutive days. (equivalent to 0.1 ml.product/kg b.w. /day).

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
The intake of medicated water depends on the clinical condition of the animals and the time of year. In order to obtain the correct dosage the concentration of enrofloxacin has to be adjusted accordingly.

According to the recommended dose, the number and weight of the animals which should be treated, the exact daily dose of veterinary medicinal product should be calculated using the following formula:

$$\text{ml of the product/L water} = \frac{\text{10 mg/kg/day x average body weight of the animals}}{\text{100 mg/ml x average water consumption (L/day)}}$$

The medicated water should be made up fresh each day just before it is offered to the animals. Sufficient access to the system of supply should be available for the animals to be treated to ensure adequate water consumption. The drinking water must be medicated throughout the treatment period, and no other water source should be available.

Use appropriate and properly calibrated dosing equipment.

9. ADVICE ON CORRECT ADMINISTRATION

See section Dosage for each species, route and method of administration.

10. WITHDRAWAL PERIOD

Meat and offal:	Chickens (broilers)	7 days
	Rabbits	2 days

Not authorised for use in birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days of coming into lay.

11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.

12. SPECIAL WARNINGS, IF NECESSARY

Special warnings for each target species

Treatment of *Mycoplasma* spp. infections may not eradicate the organism.

Special precautions for use in animals

Official and local antimicrobial policies should be taken into account when the product is used.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.

Wherever possible, fluoroquinolones should be used based on susceptibility testing.

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

Since enrofloxacin was first authorised for use in poultry, there has been widespread reduction in susceptibility of *E.coli* to fluoroquinolones and emergence of resistant organisms. Resistance has also been reported in *Mycoplasma synoviae* in the EU.

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

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.

Avoid contact with skin and eyes. Use gloves and carefully handle this product to avoid getting in contact with it when introducing it into drinking water. In case of accidental contact, rinse immediately with plenty of water.

If such symptoms as skin rash appear after being exposed to this product, seek for medical advice. Face, lip or eye swelling, as well as difficult breathing, are serious signs requiring urgent medical assistance.
Do not eat, drink or smoke whilst using the product.

Use during pregnancy, lactation or lay

Laboratory studies in rats have not produced any evidence of teratogenic effects. Studies performed in female rabbits do not show teratogenic effects for the foetus and the mother.
Studies carried out in lactating rabbits do not show toxic effects for the lactating young rabbits within the first 16 days. Rabbits older than this age have the ability to eliminate enrofloxacin.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.
Not authorised for use in birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days of coming into lay.

Interaction with other medicinal products and other forms of interaction

In vitro, an antagonism was shown, when combining fluoroquinolones with bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols.

The simultaneous application of substances containing aluminium or magnesium can impair the absorption of enrofloxacin.

Overdose (symptoms, emergency procedures, antidotes), if necessary

At the dosage of 20mg/kg b.w. (twice the recommended dosage) administered for 15 days (3 times the recommended duration of treatment) adverse reactions were not observed. In case of overdosage, the symptoms would be a weak stimulation of the spontaneous motility, so the treatment should be ceased.

Overdose by fluoroquinolones may cause sickness, vomiting and diarrhoea.

The use of fluoroquinolones during the growth phase combined with a marked and prolonged increase in the intake of drinking water, and hence active ingredient, possibly due to high temperatures, may potentially be associated with damage of the articular cartilage.

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 PRODUCTS OR WASTE MATERIALS, IF ANY

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 LABEL-LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes: 1 L and 5 L
Not all pack sizes may be marketed.

[ES]:
For animal treatment only. Veterinary medicinal product subject to veterinary prescription.
Administration under the control or direct responsibility of a veterinary surgeon.

[EL, IT, PT, CY]:
For animal treatment only. To be supplied only on veterinary prescription

EXPIRITY DATE

PACKAGE SIZE

MARKETING AUTHORISATION NUMBER

BATCH NUMBER