PARTICULARS TO APPEAR ON THE OUTER PACKAGE / PACKAGE LEAFLET

1 L / 5 L

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

Marketing authorisation holder and manufacturer responsible for batch release:
LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135 17170-Amer (Girona)
SPAIN
Tel. (34) 972 43 06 60
Fax (34) 972 43 06 61
E-mail: hipra@hipra.com

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SPECTRON 100 mg/ml solution for use in drinking water for chickens and turkeys
Enrofloxacin

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

Each ml contains:

Active substance:

Enrofloxacin……100 mg

PHARMACEUTICAL FORM:

Solution for use in drinking water.
Slightly yellowish clear solution.

4. INDICATIONS

Treatment of infections caused by the following bacteria susceptible to enrofloxacin:
Chickens
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,

Pasteurella multocida.
Turkey
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella 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, to 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, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens and turkeys.

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

For oral administration via the drinking water. This may be put directly into the header tanks, or via water proportioner systems.

Chickens and turkeys
10 mg enrofloxacin/kg bodyweight per day for 3-5 consecutive days.
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.

Medication of the water supply should be continuous during the treatment period and no other source of water should be available.
Medicated water should be made every day, immediately prior to provision. Carefully calculate the total body mass to be treated and the total daily water consumption before each treatment.
The uptake of medicated water depends on age and clinical condition of the birds, ambient temperature, and light regime. In order to obtain the correct dosage the concentration of the product should be adjusted accordingly.

Taking into consideration that 10 mg enrofloxacin per kg body weight corresponds to 0.1 ml of the product per kg body weight; the following calculation should be made to provide the required amount of the product per litre of drinking water:

$$\frac{0.1 \times \text{Average bodyweight of birds to be treated (kg)} \times \text{Number of birds}}{\text{Total water consumption (l) of the flock at the previous day}} = \text{ml product per litre of drinking water}$$

Care should be taken that the intended dose is completely ingested.
Use appropriate and properly calibrated dosing equipment.

9. ADVICE ON CORRECT ADMINISTRATION

Before use, header tanks should be emptied, thoroughly cleaned and then filled with a known volume of clean water before adding the required amount of the veterinary medicinal product. The resulting mixture should be stirred.

10. WITHDRAWAL PERIOD

Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 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

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
Keep the bottle tightly closed.

Do not use this veterinary medicinal product after the expiry date which is stated on the labe after “EXP”. The expiry date refers to the last day of that month.
Once opened, use by …
Shelf life after first opening the container: 3 months.
Shelf life after dilution according to directions: 24 hours

12. SPECIAL WARNING(S)

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.
Whenever possible, fluoroquinolones should only be used based on susceptibility testing.
Use of product deviating from the 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.
Before use, header tanks should be inspected at regular intervals for presence of dust, algae formation and sedimentation.
If there is no clinical improvement within two to three days susceptibility testing should be repeated and therapy should be changed, if appropriate.
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:
This product is an alkaline solution; personal protective equipment, including impervious gloves, should be worn when handling the product.
Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions.
In the event of eye or skin contact, rinse the affected area with clean water and if irritation occurs, seek medical attention.
People with known hypersensitivity to fluoroquinolones should avoid contact with the product.
Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the product.

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.Do not combine enrofloxacin with steroidal anti-inflammatory products.

Overdose (symptoms, emergency procedures, antidotes), if necessary:
No adverse clinical symptoms were observed in chickens and turkeys treated respectively with doses up to 10 and 6 times higher than the therapy dose.

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:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon 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

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15. OTHER INFORMATION

Pack size:
100 ml
1 L
5 L

Pack sizes authorised:
1 bottle of 100 ml
1 bottle of 1 L
1 barrel of 5 L

Not all pack sizes may be marketed.

EXP: month/year.

For animal treatment only - to be supplied only on veterinary prescription.

IE only: VPA 10846/011/001 POM Prescription Only Medicine
UK only: Vm 17533/4013 POM-V:

MA No.:

Batch:

Local Representative:
HIPRA UK AND IRELAND, Ltd.
Tel. (+44) 0115 912 4320

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SPECTRON 100 mg/ml solution for use in drinking water for chickens and turkeys

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Enrofloxacin ……100 mg

3. PHARMACEUTICAL FORM

Solution for use in drinking water.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Chickens and turkeys.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 3 months.
Shelf life after dilution according to directions: 24 hours
Once opened use by…

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the bottle tightly closed.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135 17170-Amer (Girona)
SPAIN

Local Representative:
HIPRA UK AND IRELAND, Ltd.
Tel. (+44) 0115 912 4320

16. MARKETING AUTHORISATION NUMBERS

IE only: VPA 10846/011/001 POM Prescription Only Medicine
UK only: Vm 17533/4013 POM-V:

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SPECTRON 100 mg/ml solution for use in drinking water for chickens and turkeys

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Enrofloxacin ……..…….
100 mg

3. PHARMACEUTICAL FORM

Solution for use in drinking water.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Chickens and turkeys.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 3 months.
Shelf life after dilution according to directions: 24 hours
Once opened use by…

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the bottle tightly closed.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135 17170-Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBERS

IE only: VPA 10846/011/001 POM Prescription Only Medicine
UK only: Vm 17533/4013 POM-V:

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET INCLUDED WITH THE 100 ML BOTTLE FOR:

SPECTRON 100 mg/ml solution for use in drinking water for chickens and turkeys

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

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SPECTRON 100 mg/ml solution for use in drinking water for chickens and turkeys
Enrofloxacin

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

Each ml contains:

Active substance:
Enrofloxacin ……100 mg

Slightly yellowish clear solution.

4. INDICATION(S)

Treatment of infections caused by the following bacteria susceptible to enrofloxacin:
Chickens
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,
Pasteurella multocida.

Turkey
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella 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, to 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 package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens and turkeys.

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

For oral administration via the drinking water. This may be put directly into the header tanks, or via water proportioner systems.

Chickens and turkeys
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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.

Medication of the water supply should be continuous during the treatment period and no other source of water should be available.
Medicated water should be made every day, immediately prior to provision. Carefully calculate the total body mass to be treated and the total daily water consumption before each treatment.
The uptake of medicated water depends on age and clinical condition of the birds, ambient temperature, and light regime. In order to obtain the correct dosage the concentration of the product should be adjusted accordingly. Taking into consideration that 10 mg enrofloxacin per kg body weight

corresponds to 0.1 ml of the product per kg body weight; the following calculation should be made to provide the required amount of the product per litre of drinking water:

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10. WITHDRAWAL PERIOD

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Keep the bottle tightly closed.

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Shelf life after first opening the container: 3 months.
Shelf life after dilution according to directions: 24 hours

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Tel. (+44) 0115 912 4320

Approved: 24 July 2018