ΠΑΡΑΡΤΗΜΑ 1: ΠΕΡΙΛΗΨΗ ΤΩΝ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLUMEXIL 100 mg/g, granules for use in the drinking water or liquid feed for calves, buffalo calves, foals, lambs, kid-goats, swine and piglets, rabbits, chickens.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g contains:

Active substance:

Flumequine.....100 mg

For a complete list of the excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Granules for oral solution.

4. CLINICAL PARTICULARS

4.1. Target species

Calves, buffalo calves, foals, lambs, kid-goats, swine and piglets, rabbits, chickens.

4.2. Indications for use, specifying the target species

FLUMEXIL is indicated in therapy of:

- gastrointestinal infections;
- septicemic infections;
- neonatal infections;
- respiratory infections;
- urinary infections.

More specifically, it is indicated in infections due to pathogens sensitive to flumequine, particularly:

- *E. coli*, *Salmonella* sp., *Pasteurella* sp. in young ruminants (calves, buffalo calves, lambs, kid-goats), foals, piglets, rabbits, chickens;
- *Bordetella* sp. in swine and in rabbits;
- *Proteus* sp., *Klebsiella* sp., *Enterobacter* sp. in all the above-mentioned species.

4.3. Contraindications

Do not use in animals with known hypersensitivity to the active substance or to any of the excipients.

4.4. Special warnings for each target species

Use of the product (flumequine) in poultry must comply with Commission Regulation (EC) 1177/2006 and national implementation regulations.

4.5. Special precautions for use

Special precautions for use in animals

During use of the veterinary medicinal product, is necessary to take into account official and local regulations on the use of antimicrobial substances.

If possible, the quinolones must be used exclusively on the basis of the results of a susceptibility test.

Use of such products other than according to the instructions supplied in the SPC may cause an increase in the prevalence of bacteria resistant to the quinolones and, at the same time, reduce the efficacy of treatment with other quinolones, owing to cross-resistance.

The product must not be used for prophylaxis: repeated or prolonged use of FLUMEXIL 10% should be avoided, improving management procedures and with disinfection.

Do not exceed the recommended doses.

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

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

The product should not be administered by pregnant women.

In case of contact or accidental ingestion, seek medical help immediately, showing the doctor the package leaflet or the label.

4.6. Adverse reactions (frequency and seriousness)

None reported.

4.7. Use during pregnancy, lactation or lay

It may be used during pregnancy and lactation.

4.8. Interaction with other medicinal products and other forms of interaction

Do not administer in combination with sulphonamides and trimethoprim.

4.9. Amounts to be administered and administration route

The loading dosage is 12 mg of active substance/kg b.w. in calves, buffalo calves, foals, lambs, kid-goats and chickens, 15 mg of active substance/kg b.w. in swine and piglets and 15-30 mg of active substance/kg b.w. in rabbits, followed by halved maintenance doses.

SPECIES	LOADING DOSE	MAINTENANCE DOSE
Calves, buffalo calves and foals	6 g/50 kg b.w.	3 g/50 kg b.w.
Lambs and kid-goats	0.6 g/5 kg b.w.	0.3 g/5 kg b.w.
Swine and piglets	1.5 g/10 kg b.w.	0.75 g/10 kg b.w.
Rabbits	1.5-3 g/10 kg b.w.	0.75-1.5 g/10 kg b.w.
Chickens	1.2 g/10 kg b.w.	0.6g/10 kg b.w.

FLUMEXIL should be dissolved in the drinking water or in milk or in liquid feed and administered orally, following the dosage indicated in the following table:

ANIMAL SPECIES	FEED TO BE MEDICATED	DIETARY RATION	LOADING DOSE	MAINTENANCE DOSE
Calves and buffalo calves	milk	4 litres/50 kg b.w./day	6 g/2 litres of milk	3 g/2 litres of milk
Lambs and kid-goats	milk	0.5 litres/5 kg b.w./day	0.6 g/250 ml of milk using a bottle or feeding bottle	0.3 g/250 ml using a bottle or feeding bottle
Foals	milk	——	6 g/50 kg b.w. in 250 ml of milk using a feeding bottle	3 g/50 kg b.w. in 250 ml of milk using a feeding bottle
Swine	dry matter of liquid feed	3 kg/100 kg b.w./day	15g/l.5 kg of dry matter of liquid feed	7g/l.5 kg of dry matter of liquid feed
Chickens	water	10 litres/80 kg b.w./day	9.6 g/5 litres of water	4.8 g/5 litres of water
Rabbits	water	16 litres/100 kg b.w./day	15-30 g/8 litres of water	7.5-15 g/8 litres of water

The loading dose (first dose) is followed by maintenance doses, administered every 12 hours.

Remission of the symptoms must be observed within 36-48 hours of the start of therapy.
Therapy must be suspended 12-24 hours after complete remission of the symptoms
If no remission of the symptoms is observed within the above-mentioned period of time, the diagnosis and therapy should be re-examined.
To avoid under- or over-dosing, the body weight must be determined as precisely as possible.

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

At a dosage greater than 15 mg/kg, in growing animals, the quinolones can cause changes to joint cartilages.

4.11. Withdrawal periods

Meat and offal:

Calves, buffalo calves, foals, lambs, kid-goats, swine and piglets: 8 days

Rabbits, chickens: 6 days

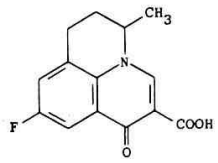
Use is not permitted in layer hens producing eggs intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: quinolone and quinoxalines - other quinolones.
ATCvet Code: QJ01MB07

5.1. Pharmacodynamic properties

Flumequine is a chemotherapeutic agent belonging to the quinolone family, the structural formula of which is the following:



The fluorine present in the molecule has the property of accentuating the activity of the medicinal product.
Flumequine acts by inhibiting protein synthesis in sensitive bacteria, blocking the enzyme DNA-polymerase and its effects are of the bactericidal type.
It is active against *Salmonella* sp., *E. coli*, *Pasteurella* sp., *Pseudomonas* sp., *Proteus* sp., *Klebsiella* sp., *Bordetella* sp., *Enterobacter* sp. and *Staphylococcus* sp.

Like most antibacterial products, flumequine can also induce the phenomenon of bacterial resistance, which is established slowly and progressively.
FLUMEXIL must therefore be used exclusively in case of real need and always at full dosage and for at least 12 or 24 hours after remission of symptoms.
Flumequine possesses low acute and chronic toxicity and its use is characterized by negligible undesirable effects, differing in this from other compounds belonging to the same quinolone family.

5.2. Pharmacokinetic particulars

Flumequine distributes rapidly to the liver, kidneys, muscle, glands, lymph nodes, colon, jejunum and eyes. The plasma half-life time varies between 5 and 7 hours, depending on the species. It is predominantly excreted as is, with a small part in inactivated form. The route of excretion is renal, a small part being eliminated in faeces.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium carbonate anhydrous
Lactose monohydrate

6.2. Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3. Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution according to directions: 24 hours.

6.4. Special precautions for storage

Protect from light.

6.5. Nature and composition of immediate packaging

1 kg polyethylene or polypropylene jars with under cap and closure with tear-off safety seal.

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
FATRO S.p.A. - Via Emilia, 285 - Ozzano Emilia (Bologna), Italy

8. MARKETING AUTHORISATION NUMBER
14564

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Date of first authorization: 18/01/1994
Date of renewal: 25/04/2013

10. DATE OF REVISION OF THE TEXT
25/04/2013

PROHIBITION OF SALE, SUPPLY AND/OR USE

DISPENSING