Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Flumisol Oral Solution 100 mg/ml.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance

Flumequine	100.0 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
A pale yellow to yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Poultry.

4.2 Indications for use, specifying the target species

For the treatment of colibacillosis and infections of *S. typhimurium* and *S. enteritidis* which are sensitive to Flumequine in broiler chickens.

Use where clinical experience, supported where possible be sensitivity testing of the causal organism, indicates Flumequine as the drug of choice.

4.3 Contraindications

Do not use in laying hens producing eggs for human consumption.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Official and local antimicrobial policies should be taken into account when the product is used.
Whenever possible, quinolones should only be used based on susceptibility testing.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the quinolones and may decrease the effectiveness of treatment with other (fluoro)quinolones due to the potential for cross resistance.

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

- Irritant for skin and eyes. Wash any splashes from skin or eyes immediately.
- Wear impervious gloves when handling the product.
- Wash hands and exposed skin after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

To ensure a correct dosage, body weight should be determinated as accurately as possible. Dosage scheme is 18 mg flumequine / kg bodyweight / day, administered in a continuous mode, over a period of 24 hours or in a pulse mode over a period of 6 hours. Treatment duration is 5 days. Flumisol must be administered by oral route, *via* drinking water as 0.18 ml of Flumisol per kg of bodyweight and mixed into an appropriate volume of drinking water.

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

Poultry: No side effects were observed during the tolerance studies.
Prolonged administration (twice the recommended period of treatment) of Flumisol at 18 mg/kg induces a slight and reversible decrease in water consumption.

4.11 Withdrawal Period(s)

Eggs: Not to be consumed.
Meat and offal: 2 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, flumequine.
ATCvet code QJ01MB07

5.1 Pharmacodynamic properties

Flumequine is active against Gram (-) bacteria.

Flumequine is a synthetic antibacterial agent which belongs to the Quinolone family. It is the first fluorinated quinolone, with a fluorinate atom which enhances its intrinsic activity and antibacterial spectrum.

It acts on nucleic acids by stopping DNA replication of the bacteria. The exact molecular target is the DNA gyrase enzyme involved in the DNA spiral formation. Antibacterial activity of Flumequine is the result of the combination of bacterial cell penetration and DNA gyrase-inhibiting activities.

5.2 Pharmacokinetic properties

Absorption and distribution
Flumequine is well absorbed. Its bio-availability factor approximates 70 - 75%. Tmax is reached after more or less 13 - 14 h and Cmax varies from 1.7 to 3.7 mg/l. Pharmacokinetic parameters are linearly related to the administered dose of flumequine.
No accumulation in blood and no enzymatic induction or inhibition are noticed.

Biotransformation
Flumequine is essentially metabolised into 7-hydroxyfumequine in the kidney.

Elimination
Flumequine has a relatively slow elimination phase. Its half-life approximates 5 - 6 hours.
Flumequine is mainly excreted via urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Hydroxide
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years. Shelf-life after first opening the immediate packaging: 6 months.
The product is stable for 5 days when diluted in tap water.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

1 or 5 litre high density polyethylene screw bottle. The tamper-proof screw capsules are fitted with a measuring device. The cap and the measuring device are in polyethylene and the seal is in expanded polyethylene. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Ceva Animal Health Limited
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HP7 9FB
UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10995/018/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

10th November 2011