Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Florvio 23 mg/ml solution for use in drinking water for pigs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Florfenicol	23 mg

Excipients:

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for use in drinking water.
Clear, colourless to yellow, slightly viscous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Pig.

4.2 Indications for use, specifying the target species

Treatment and prevention at the group level where clinical signs are present of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol. The presence of the disease should be established in the herd before initiating treatment.

4.3 Contraindications

Do not use in boars intended for breeding purposes.
Do not administer in cases of previous allergic reactions to florfenicol.

4.4 Special warnings for each target species

The treated pigs should be placed under special observation. On each of the five days of treatment, untreated drinking water should not be given until the full daily amount of medicated drinking water has been ingested by the pigs. If there is no significant improvement after 3 treatment days, the diagnosis should be reviewed and if necessary the treatment should be changed.

4.5 Special precautions for use

Special precautions for use in animals

The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies. Inappropriate use of the product may increase the prevalence of bacteria resistant to florfenicol and may decrease the effectiveness of treatment with florfenicol, due to the potential for cross-resistance.
Treatment should not exceed 5 days.
Do not use in case of resistance.

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

People with known hypersensitivity to polyethylene glycols should avoid contact with the veterinary medicinal product.
In case of accidental spillage onto skin rinse with water.

Other precautions:
Manure from treated pigs should be stored for 27 days prior to spreading and incorporating into land.

4.6 Adverse reactions (frequency and seriousness)

A slight reduction of water consumption by the animals, dark brown faeces and constipation may be observed during treatment.

Commonly observed adverse effects are diarrhoea and/or peri-anal and rectal erythema/oedema which may affect approximately 40% of the animals. These effects are transient. In a few of the affected animals, prolapse of the rectum, that resolves without treatment, may be observed.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in pigs have not produced any evidence of foetotoxic effects.
The safety of the veterinary medicinal product in sows has not been established during pregnancy and lactation.

The use is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

Oral route in drinking water.

Pigs: 10 mg florfenicol per kg body weight per day for 5 consecutive days. This dose is equivalent to 0.44 ml of the product per kg body weight per day.

The amount of the product can be calculated based on the Total Body Weight of herd to be treated (TBW) and the Total Water Consumption of the herd in 24 hr (TWC) with the following formula:

The product (litre) = $\frac{\text{10 x TBW (kg)}}{\text{23 x TWC (litre)}}$ per 1000 litre of medicated water in the tank

If a proportioner set at P% is used, then the formula is

The product (litre) = $\frac{\text{10 x TBW (kg)}}{\text{23 x TWC (litre)}} \times \frac{1}{P(\%)}$ per 10 litre of pre-diluted medicated water in the proportioner

Dilute the calculated volume of the product with water to a total volume of 10 litre in the proportioner. Do not use this product at any other proportioner setting.

The appropriate quantity of medicated water or pre-diluted medicated water should be prepared based on the daily water consumption.

Medicated drinking water should be replaced every 24 hours.

Check for completeness of solution before administration.

Specific examples are given below:

FOR BULK TANK: To treat pigs drinking 10% of their bodyweight, at the dose of 10 mg/kg: add the product to the drinking water in the bulk tank. Use one bottle (2.17 litre) of product for every 500 litre of water and mix thoroughly. This corresponds to a 100 mg/litre drinking water concentration.

FOR PROPORTIONER (2.17 litre): Two convenient proportioner settings for the use of florfenicol in the drinking water are 10% and 1%.

A. Ten percent setting:

To treat 5,000 kg of pigs, drinking 10% of their bodyweight, at the dose rate of 10 mg/kg:

1. Dilute the content of the bottle to 4 litre with drinking water.
2. Mix thoroughly.
3. Empty the diluted product in the proportioner.
4. Dilute to 50 litre with drinking water.
5. Mix thoroughly.
6. Set the proportioner on 10%.
7. Turn on the proportioner.

B. One percent setting:

To treat 5,000 kg of pigs, drinking 8% of their body weight, at the dose rate of 10 mg/kg:

1. Dilute the content of the bottle to 4 litre with drinking water.
2. Mix thoroughly.
3. Empty the diluted product in the proportioner.
4. Mix thoroughly.
5. Set the proportioner on 1%.
6. Turn on the proportioner.

FOR PROPORTIONER (0.54 litre): Two convenient proportioner settings for the use of florfenicol in the drinking water are 10% and 1%.

A. Ten percent setting:

To treat 1, 250 kg of pigs, drinking 10% of their bodyweight, at the dose rate of 10 mg/kg:

1. Dilute the content of the bottle to 1 litre with drinking water.
2. Mix thoroughly.
3. Empty the diluted product in the proportioner.
4. Dilute to 12.5 litre with drinking water.
5. Mix thoroughly.
6. Set the proportioner on 10%.
7. Turn on the proportioner.

B. One percent setting:

To treat 1, 250 kg of pigs, drinking 8% of their body weight, at the dose rate of 10 mg/kg:

1. Dilute the content of the bottle to 1 litre with drinking water.
2. Mix thoroughly.
3. Empty the diluted product in the proportioner.
4. Mix thoroughly.
5. Set the proportioner on 1%.
6. Turn on the proportioner.

Solutions should not be prepared at concentrations between 1.2 g and 12 g florfenicol per litre.

The uptake of medicated water depends on several factors including the clinical state of the animals and local conditions such as ambient temperature and humidity. In order to obtain the correct dosage water uptake has to be monitored and the concentration of florfenicol has to be adjusted accordingly. If however it is not possible to obtain sufficient uptake of medicated water animals should be treated parenterally.

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

In case of overdosing, a decrease in weight gain, food and water consumption, peri-anal erythema and oedema and modification of some haematological and biochemical parameters indicative of dehydration may be observed.

4.11 Withdrawal Period(s)

Meat and offal: 20 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Amphenicols

ATC Vet Code: QJ01BA90

5.1 Pharmacodynamic properties

Florfenicol is a broad-spectrum synthetic antibiotic in the phenicol group that is active against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibition of protein synthesis at the ribosomal level and is bacteriostatic. However, bactericidal activity has been demonstrated in-vitro against *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* when florfenicol is present at concentrations above the MIC (µg/ml) for up to 12 hours.

In-vitro testing has shown that florfenicol is active against the bacterial pathogens most commonly isolated in respiratory diseases in pigs, including *Actinobacillus pleuropneumoniae* and *Pasteurella multocida.*

5.2 Pharmacokinetic properties

After administration to pigs by gavage at 15 mg/kg under experimental conditions, absorption of florfenicol was variable but peak serum concentrations of approximately MIC 5 µg/ml were reached approximately 2 hours after dosing. The terminal half-life was between 2 and 3 hours. When pigs were given free access, for 5 days, to water medicated with florfenicol at a concentration of 100 mg florfenicol per litre of water, serum concentrations of florfenicol exceeded MIC 1 µg/ml for the entire 5 day treatment period except for a couple of short excursions below MIC 1 µg/ml.

After absorption and distribution, florfenicol is extensively metabolised by pigs and rapidly eliminated, primarily in urine.

After parenteral dosing of florfenicol to pigs, it has been shown that lung concentrations are similar to serum concentrations.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 300

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after dilution or reconstitution according to directions (in-use): 24 hours
Do not use the veterinary medicinal product for more than 5 hours with proportioners, if galvanised piping is used.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Pack Sizes:	1 litre bottle containing 0.54 litre 4 litre bottle containing 2.17 litre
Containers:	HDPE bottles
Closures:	Polypropylene Screw Caps with a liner.

Not all pack sizes may be marketed.

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

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

Elanco Europe Ltd.
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10397/022/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th December 2012

10 DATE OF REVISION OF THE TEXT

June 2016