SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELECTAN ORAL 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 the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for use in drinking water.
A slightly yellowish and clear solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

Pigs: Treatment and metaphylaxis 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 preventive treatment.

4.3 Contraindications

Do not use in boars intended for breeding purposes.

Do not use in case of known hypersensitivity to the active substance or to the excipient.

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, unmedicated drinking water should not be given until the full daily amount of medicated drinking water has been ingested by pigs.

If there are no signs of improvement after three days of treatment, the diagnosis should be reviewed and, if necessary, the treatment changed.

Animals showing a decreased water intake and/or a poor general condition should be treated by the parenteral route.

4.5 Special precautions for use

Special precautions for use in animals
The veterinary medicinal product should be used in conjunction with susceptibility testing.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the florfenicol.
Official and local antimicrobial policies should be taken into account when the product is used.
Treatment should not exceed 5 days.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to florfenicol or 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 3 months prior to spreading and incorporating into land.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases 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 very rare cases, prolapse of the rectum, that resolves without treatment, may be observed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy:
Laboratory studies in animals have not produced any evidence of potential embryotoxic or foetotoxic effects.
The use is not recommended during pregnancy.

Lactation:
The use is not recommended during 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 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.

The required amount of the florfenicol concentrate solution can be calculated based on the total body weight of herd to be treated and the total water consumption of the herd in 24 hr with the following formula:

$$Volume\ (ml\ product / L\ water) = \frac{0.44\,ml \times Total\ Body\ Weight\ (kg)}{Total\ Water\ Intake\ (L)}$$

Considering that a pig drinks approximately 10% of its body weight per day, the following dose is recommended: 4.4 ml of the product / L water.

After calculation of the required amount of product, use a graduated device to measure the exact amount and thoroughly mix the volume of the product with the appropriate quantity of water immediately before use. Only sufficient medicated drinking water should be prepared to cover the daily requirements. To ensure a correct dosage, measurements should be determined as accurately as possible to avoid underdosing.

Treatment should continue for 5 consecutive days.
Medicated drinking water should be replaced every 24 hours.

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

$$Volume\ product\ (L) = \frac{0.44\,ml \times Total\ Body\ Weight\ (kg)}{1000}$$

$$Volume\ water\ (L) = \frac{Total\ Water\ Intake\ (L) \times P\%}{100} - Vproduct\ (L)$$

Instructions are given below:

Bulk tank	Proportioners
1. Measure ***Volume*** of product per litre of water and empty it in the bulk tank. 2. Mix thoroughly and begin administration.	1. Check the concentration according to the warning below. 2. Measure ***Volume product*** and empty it in the proportioner. 3. Measure ***Volume water*** and empty it in the proportioner. 4. Mix thoroughly. 5. Set the proportioner on your setting (i.e. 10% or 1%) and turn it on.

If electric pumps are used instead of hydraulic ones, the flow must be controlled in order to avoid underdosing.

Warning: Solutions with concentrations comprised between 1.2 and 12 g of florfenicol per litre precipitate. In this case mix the product directly in the bulk tank or change the proportioner setting. Use the following formula to check the concentration:

I
II
III

$$g/L = \frac{Total\ body\ Weight\,(kg)}{Total\ Water\,(L) \times P\%}$$

IV 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 PROPERTIES

Pharmacotherapeutic group: Antimicrobials for systemic use, amphenicols.
ATCvet 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 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.*

Reported MIC_{90} values (2008 – 2010) for *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* were found to be 0.5 µg/mL. For *A. pleuropneumoniae* and *P. multocida*, the CLSI breakpoint of resistance for swine respiratory disease is ≥8 µg/ml. Cross-resistance to chloramphenicol and florfenicol mediated by a gene (*flo*R) that codes for an efflux protein and is carried on plasmids has been observed in isolated cases of porcine Pasteurellae.

5.2 Pharmacokinetic particulars

After administration to pigs by gavage at 15 mg/kg under experimental conditions, absorption of florfenicol was variable but peak serum concentrations of approximately 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 the product at a concentration of 100 mg florfenicol per litre of water, serum concentrations of florfenicol exceeded 1 µg/mL for the entire 5 day treatment period except for a couple of short excursions below 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: 1 year.
Shelf life after first opening the immediate packaging: 28 days.
Shelf life after dilution according to directions: 24 hours.

6.4. Special precautions for storage

Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

The product is filled in 5 L HDPE plastic barrels closed with HDPE plastic screw-on caps and a polyethylene 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 product should be disposed of in accordance with local requirements.
The product should not be allowed to enter surface water as it has harmful effects on aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 17533/4014

9. DATE OF FIRST AUTHORISATION

28 April 2011

10. DATE OF REVISION OF THE TEXT

April 2016

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

Approved: 13 April 2016