

PARTICULARS TO APPEAR ON THE OUTER PACKAGE / PACKAGE LEAFLET

5 L

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELECTAN ORAL 23 mg/ml solution for use in drinking water for pigs
Florfenicol.

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

Composition per ml:

Active substance:

Florfenicol..... 23 mg

PHARMACEUTICAL FORM:

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

PACKAGE SIZE:

5 L

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

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 resolve 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).

If you notice any serious effects or other effects not mentioned in this label, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs.

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

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:

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

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:

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

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

Instructions are given below:

Bulk tank	Proportioners
1. Measure Volume of product per litre of water and empty it in the bulk tank.	1. Check the concentration according to the warning below.
2. Mix thoroughly and begin administration.	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:

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

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Meat and offal: 20 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP: month/year.

Shelf-life after first opening the container: 28 days.

Shelf life after dilution according to directions: 24 hours.

Once broached, use by:

After opening store the product in the vertical position.

12. SPECIAL WARNING(S)

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.

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.

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.

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.

Incompatibilities:

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

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

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

Batch:

EXP: month/year