SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELECTAN
300 mg/ml solution for injection for cattle and swine.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance
Florfenicol …… 300 mg
Excipients
N-methyl pyrrolidone ……..……308 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
A slightly yellowish and clear solution.

4. CLINICAL PARTICULARS

4.1. Target species

Cattle and swine.

4.2. Indications for use, specifying the target species

Diseases caused by florfenicol susceptible bacteria:

Cattle:
Therapeutic treatment of respiratory tract infections in cattle due to *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni.*

Swine:
Treatment of acute outbreaks of respiratory disease caused by strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

4.3. Contraindications

Do not administer to adult bulls or boars intended for breeding purposes.
Do not administer to animals with known hypersensitivity to the active substance or to any of the excipients.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for use in animals
Do not use in piglets of less than 2 kg.
Swab the septum before removing each dose.
Use a dry, sterile syringe and needle.
Use of the veterinary medicinal product should be based on susceptibility testing and take into account official and local antimicrobial policies.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the florfenicol and may decrease the effectiveness of treatment with other amfenicols, due to the potential for crossresistance.

Special precaution to be taken by the person administering the medicinal product to animals
Care should be taken to avoid accidental self-injection.
Avoid contact with eyes and skin.
If eye exposure occurs, flush eyes immediately with clean water.
If skin exposure occurs, wash the affected area with clean water.
Wash hands after use.
People with known hypersensitivity to florfenicol should avoid contact with the veterinary medicinal product.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

4.6. Adverse reactions (frequency and seriousness)

Cattle
A decrease in food consumption and transient softening of the faeces may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment.

Administration of the veterinary medicinal product may cause inflammatory lesions at injection site which persist for up to 14 days.

Swine
Commonly observed adverse effects are transient diarrhoea and/or peri-anal and rectal erythema/oedema which may affect 50% of the animals. These effects can be observed for one week.

Transient swelling lasting up to 5 days may be observed at the site of injection. Inflammatory lesions at the injection site may be seen for up to 28 days.

4.7. Use during pregnancy, lactation, or lay

The safety of the veterinary medicinal product has not been established in cattle and swine during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

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

None known.

4.9. Amounts to be administered and administration route

Cattle:
20 mg/kg bodyweight (1 ml of the product per 15 kg) by intramuscular route to be administered twice 48 hours apart.
For treatment of cattle over 150 kg body weight, divide the dose so that no more than 10 ml are injected at one site.

Swine:
15 mg/kg bodyweight (1 ml of the product per 20 kg) by intramuscular injection into the neck muscle twice at 48 hours intervals.
For treatment of swine over 60 kg body weight, divide the dose so that no more than 3 ml are injected at one site.

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

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

In swine, after administration of 3 times the recommended dose or more a reduction in feeding, hydration and weight gain has been observed. After administration of 5 times the recommended dose or more vomiting has also been noted.

4.11. Withdrawal period(s)

Cattle:
Meat and offal: 30 days.
Not permitted for use in lactating animals producing milk for human consumption.

Swine:
Meat and offal: 18 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use (Amphenicols).
ATCvet code: QJ01BA90.

5.1. Pharmacodynamic properties

Florfenicol is a systemic broad spectrum antibiotic effective against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibiting protein synthesis at the ribosomal level and is bacteriostatic. However, in vitro studies of florfenicol demonstrate bactericidal activity against *Mannheimia haemolytica*, *Pasteurella multocida*, *Actinobacillus pleuropneumoniae*, and *Histophilus somni*.

In vitro testing has shown that florfenicol is active against the bacterial pathogens most commonly isolated in respiratory diseases in cattle (including *Pasteurella multocida*, *Mannheimia haemolytica* and *Histophilus somni*) and in pigs (including *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*).

5.2. Pharmacokinetic particulars

Cattle:
In cattle, intramuscular administration at the recommended dose of 20 mg/kg maintains efficacious blood levels for 48 hours. Maximum mean serum concentration (Cmax) of 2.55 µg/ml occurs at 4.7 hours (Tmax) after dosing. The mean serum concentration 24 hours after dosing was 1.4 µg/ml. The harmonic mean elimination half-life was 26.2 hours.

Pigs:
After initial intramuscular administration of florfenicol, maximum serum concentrations of between 1.9 and 3.1 µg/ml are reached after 2.2 hours and the concentrations deplete with a terminal mean half-life of 35.5 hours. After a second intramuscular administration, maximum serum concentrations of between 2.0 and 8.1 µg/ml are reached after 1.7 hours. Florfenicol concentrations achieved in lung tissue reflect plasma concentrations, with a lung:plasma concentration ratio of approximately 1.

After administration to pigs by intramuscular route, florfenicol is rapidly excreted, primarily in urine. The florfenicol is extensively metabolised.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

N-methyl pyrrolidone.
Glycerol formal.

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 first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Keep container in outer carton.

6.5 Nature and composition of immediate packaging

The product is bottled in 100 ml colourless Type II glass bottles and 50, 100 and 250 ml plastic bottles, closed with Type I polymeric elastomer stopper with aluminium cap.
One bottle of 50, 100 or 250 ml is available in a cardboard box.
Also clinical pack sizes are available:
10 x 100 ml, 10 x 250 ml, 12 x 100 ml, and 12 x 250 ml.
Not all pack sizes may be marketed.

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

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

8. MARKETING AUTHORISATION NUMBER

Vm 17533/4006

9. DATE OF FIRST AUTHORISATION

19 December 2007

10. DATE OF REVISION OF THE TEXT

October 2023

Approved 03 October 2023