1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELECTAN 300 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Florfenicol 300 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
N-methyl pyrrolidone	308 mg
Glycerol formal	

A slightly yellowish and clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

Diseases caused by florfenicol susceptible bacteria:

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

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

3.3 Contraindications

Do not use in adult bulls or boars intended for breeding purposes.
Do not use in cases of hypersensitivity to the active substance or to any of the excipient(s).
Do not use in piglets of less than 2 kg.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 in accordance with official, national 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 cross-resistance.

Special precautions to be taken by the person administering the veterinary 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.

Special precautions for the protection of the environment:

The use of this veterinary medicinal product may pose a risk for terrestrial plants, cyanobacteria and groundwater organisms.

3.6 Adverse events

Cattle:

Very rare (<1 animals / 10 000 animals treated):	Injection site lesion[1], Injection site inflammation[1] Reduced food intake[2] Soft stool[2,3]

[1] Persists for up to 14 days.
[2] The treated animals recover quickly and completely upon termination of treatment.
[3] Transient.

Pigs:

Very common (>1 / 10 animals treated):	Diarrhoea[1,2] Oedematous erythema[2,3]
Very rare (<1 animals / 10 000 animals treated):1	Injection site swelling[4], Injection site lesion[5], Injection site inflammation[5]

[1] Transient.
[2] May affect 50% of the animals and can be observed for one week.
[3] Perianal, rectal.
[4] Transient, lasting up to 5 days.
[5] May be seen for up to 28 days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy, lactation and fertility:
The safety of the veterinary medicinal product has not been established 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. See also section 3.3.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular use.

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.

Pigs:
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 pigs 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In pigs, 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable

3.12 Withdrawal periods

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

Pigs:
Meat and offal: 18 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01BA90.

4.2 Pharmacodynamics

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*).

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

Keep the bottles in the outer carton.

5.4 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.

Package size:
Cardboard box with 1 bottle of 50 ml.
Cardboard box with 1 bottle of 100 ml.
Cardboard box with 1 bottle of 250 ml.
Cardboard box with 10 bottles of 100 ml.
Cardboard box with 10 bottles of 250 ml.
Cardboard box with 12 bottles of 100 ml.
Cardboard box with 12 bottles of 250 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as florfenicol may be dangerous for fish and other aquatic organisms.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10846/008/001

8. DATE OF FIRST AUTHORISATION

15/02/2008

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

05/09/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).