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

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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{DD/MM/YYYY}

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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 bottle of 100 ml.
Cardboard box with 10 bottle of 250 ml.
Cardboard box with 12 bottle of 100 ml.
Cardboard box with 12 bottle of 250 ml.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELECTAN 300 mg/ml, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Florfenicol . 300 mg

3. PACKAGE SIZE

1 x 50 ml
1 x 100 ml
1 x 250 ml
10 x 100 ml
12 x 100 ml
10 x 250 ml
12 x 250 ml

4. TARGET SPECIES

Cattle and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Once broached, use by……

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottles in the outer carton.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml
Bottle of 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELECTAN 300 mg/ml, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Florfenicol ……. 300 mg

3. TARGET SPECIES

Cattle and pigs.

4. ROUTES OF ADMINISTRATION

Intramuscular use.

5. WITHDRAWAL PERIODS

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.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.
Once broached, use by……

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottles in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

100 ml
250 ml

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Bottle of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELECTAN

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Each ml contains:
Florfenicol ……. 300 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Once broached, use by……

5. PACKAGE SIZE

50 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:
Florfenicol 300 mg

Excipients:
N-methyl pyrrolidone 308 mg

A slightly yellowish and clear solution.

3. Target species

Cattle and pigs.

4. Indications for use

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*.

5. Contraindications

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

6. Special warnings

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.

Pregnancy and lactation:
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects.
The safety of the veterinary medicinal product has not been established in cattle and pigs 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.

Overdose:
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.

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

7. 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 (swelling, redness) [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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

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

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the bottles in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
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.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

16. Contact details

Marketing authorisation holder, and manufacturer responsible for batch release and contact details to report suspected adverse events:

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona) SPAIN
Tel. +34 972 43 06 60

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information