# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

50 ml
100 ml
250 ml

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELECTAN 300 mg/ml, solution for injection for cattle and swine
Florfenicol

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Florfenicol …… 300 mg

## 3. PHARMACEUTICAL FORM

Solution for injection.

## 4. PACKAGE SIZE

50 ml
100 ml
250 ml

## 5. TARGET SPECIES

Cattle and swine.

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

## 8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle: Meat and offal: 30 days.
Not permitted for use in lactating animals producing milk for human consumption.
Swine: Meat and offal: 18 days.

## 9. SPECIAL WARNING(S), IF NECESSARY

## 10. EXPIRY DATE

Exp:
Shelf life after first broaching the container: 28 days.
Once opened, use by:

## 11. SPECIAL STORAGE CONDITIONS

Keep container in outer carton.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 AMER (GIRONA)
SPAIN

Local Representative:
HIPRA UK AND IRELAND, Ltd.
Innovation Center, Office 503
BioCity Nottingham
Pennyfoot Street
Nottingham
NG1 1GF - UNITED KINGDOM
e-mail: ukandireland@hipra.com

## 16. MARKETING AUTHORISATION NUMBER

Vm 17533/4006. POM-V

## 17. MANUFACTURER'S BATCH NUMBER

Batch:

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

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

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELECTAN 300 mg/ml, solution for injection for cattle and swine
Florfenicol

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

**Each ml contains:**
Florfenicol ……..…….. 300 mg

## 3. PHARMACEUTICAL FORM

Solution for injection.

## 4. PACKAGE SIZE

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

## 5. TARGET SPECIES

Cattle and swine.

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

## 8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle: Meat and offal: 30 days.
Not permitted for use in lactating animals producing milk for human consumption.
Swine: Meat and offal: 18 days.

## 9. SPECIAL WARNING(S), IF NECESSARY

## 10. EXPIRY DATE

Exp:
Shelf life after first broaching the container: 28 days.

## 11. SPECIAL STORAGE CONDITIONS

Keep container in outer carton.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.
The veterinary medicinal product should not enter water courses as florfenicol may be dangerous for fish and other aquatic organisms.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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## 16. MARKETING AUTHORISATION NUMBER

Vm 17533/4006. POM-V

## 17. MANUFACTURER'S BATCH NUMBER

Batch:

# PACKAGE LEAFLET FOR:

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

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

Marketing authorisation holder and manufacturer responsible for batch release:
LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 AMER (GIRONA)
SPAIN

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

SELECTAN is a slightly yellowish and clear solution for injection containing:
Florfenicol …… 300 mg/ml
N-methyl pyrrolidone ……..…… 308 mg/ml

## 4. INDICATION(S)

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*.

## 5. CONTRAINDICATIONS

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

## 6. ADVERSE REACTIONS

**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 upen termination of treament. Administration of the product may cause inflammatory lesions at injection site which persist for 14 days.

**Swine:** commonly observed adverse reaction 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 up to 28 days.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Cattle and swine.

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

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.

## 9. ADVICE ON CORRECT ADMINISTRATION

## 10. WITHDRAWAL PERIOD

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

Swine:
Meat and offal: 18 days.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use after the expiry date stated on the label after Exp.
Shelf-life after first opening the container: 28 days
Keep container in outer carton.

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 WARNING(S)

The use of the veterinary medicinal product should be based on susceptibility testing and take into account official and local antimicrobial policies.
Do not use in piglets of less than 2 kg.
Swab the septum before removing each dose.
Use a dry, sterile syringe and needle.
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.
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.
In swine, after overdosages, a reduction in feeding and hydration, weight gain and vomiting has been observed.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
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.
The use of this veterinary medicinal product may pose a risk for terrestrial plants, cyanobacteria and groundwater organisms.

### USER WARNING(S)

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.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
The veterinary medicinal product should not enter water courses as florfenicol may be dangerous for fish and other aquatic organisms.

## 14. PID LINK (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

## 15. OTHER INFORMATION

Box with 1 bottle of 50 ml.
Box with 1 bottle of 100 ml.
Box with 1 bottle of 250 ml.
Pack with 10 bottles of 100 ml.
Pack with 10 bottles of 250 ml.
Pack with 12 bottles of 100 ml.
Pack with 12 bottles of 250 ml.
Not all pack sizes may be marketed.

FOR ANIMAL TREATMENT ONLY
TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION
Vm 17533/4006. POM-V: Prescription Only Medicine

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Innovation Center, Office 503
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NG1 1GF - UNITED KINGDOM
e-mail: ukandireland@hipra.com

Approved: 04 July 2024

*Gavin Hall*