

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SPECTOLIKEL 50/100 mg/ml solution for injection for calves, sheep and pigs (PT)
SPECTOLIPHEN 50/100 mg/ml solution for injection for calves, sheep and pigs (BE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Lincomycin.....50 mg
(equivalent to 54.47 mg of lincomycin hydrochloride (dried substance)).
Spectinomycin.....100 mg
(equivalent to 129.45 mg of spectinomycin sulphate (dried substance)).

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl Alcohol (E1519)	9 mg
Sodium hydroxide	
Hydrochloric acid	
Water for injections	

A colourless sterile solution.

3. CLINICAL INFORMATION

3.1 Target species

Non-ruminating calves, sheep, pigs.

3.2 Indications for use for each target species

Treatment of infections caused by bacteria sensitive to lincomycin and/or spectinomycin.

Non-ruminating calves:

- Treatment of respiratory infections caused by bacteria sensitive to lincomycin and/or spectinomycin.

Sheep:

- Treatment of respiratory infections caused by bacteria sensitive to lincomycin and/or spectinomycin.
- Treatment of infections caused by *Mycoplasma spp.* sensitive to lincomycin and/or spectinomycin.

Pigs:

- Treatment of enteric adenomatosis (ileitis) caused by *Lawsonia intracellularis*.
- Treatment of dysentery caused by *Brachyspira hyodysenteriae*.

- Treatment of infections caused by *E. coli* sensitive to lincomycin and/or spectinomycin.
- Treatment of infections caused by *Mycoplasma spp.* sensitive to lincomycin and/or spectinomycin.
- Treatment of infectious arthritis caused by bacteria sensitive to lincomycin and/or spectinomycin.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in rabbits, hamsters, guinea pigs, chinchillas or horses as this could result in severe gastro-intestinal disturbance.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The administration of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information about susceptibility of the target bacteria.

Administer with care in animals with background of allergic signs.

Do not administer higher doses than those recommended in sheep at the end of pregnancy or the beginning of lactation.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Lincomycin and spectinomycin can cause hypersensitivity (allergy) after injection, inhalation, ingestion or spillage onto skin.

Allergic reactions to these substances can be severe.

People with known hypersensitivity to these antibiotics should avoid contact with the veterinary medicinal product.

Care should be taken when handling the veterinary medicinal product to avoid any risk of exposure.

In case of exposure to the veterinary medicinal product, symptoms such as cutaneous eruption can occur. Seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of face, lips or lids or breathing difficulties are more severe signs and need urgent medical care.

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable

3.6 Adverse events

Non-ruminating calves, sheep, pigs.

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Soft stool ¹ Injection site reaction ² Neuromuscular disorder ³
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¹ Softening of stools can be observed. It is normally transient and recovers within few days without treatment.

²The administration of this veterinary medicinal product may cause local discomfort upon injection.

³Lincosamides and aminoglycosides can induce neuromuscular blocking.

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

There are no studies carried out in pregnant and lactating females. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Concomitant administration with general anaesthetics or neuromuscular blocking agents could potentiate the neuromuscular blocking.

3.9 Administration routes and dosage

Intramuscular use (i.m.)

Non-ruminating calves:

5 mg of lincomycin and 10 mg spectinomycin per kg bw (corresponding to 1 ml of the veterinary medicinal product/10 kg bw) intramuscularly, twice daily for the first day followed by once daily for 3-5 days.

Sheep:

5 mg of lincomycin and 10 mg spectinomycin per kg bw (corresponding to 1 ml of the veterinary medicinal product/10 kg bw) intramuscularly, once daily for 3-5 days.

Pigs:

5 mg of lincomycin and 10 mg spectinomycin per kg bw (corresponding to 1 ml of the veterinary medicinal product/10 kg bw) intramuscularly, to be repeated, if necessary, 24 hours later and for 5 days maximum.

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

Do not puncture the stopper more than 30 times. Otherwise, automatic syringe equipment, or a suitable draw-off needle, should be used to avoid excessive puncturing of the closure.

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

None known.

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

Non-ruminating calves:

Meat and offal: 23 days

Sheep:

Meat and offal: 15 days

Milk: not authorised for use in animals producing milk for human consumption.

Pigs:

Meat and offal: 14 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01FF52

4.2 Pharmacodynamics

The combination lincomycin-spectinomycin is active against a wide range of Gram-positive and Gram-negative bacteria and mycoplasma. Lincomycin is especially active against Gram-positive bacteria (such as *Streptococcus* and *Staphylococcus*) and *Mycoplasma*. Spectinomycin is more specifically active against Gram-negative bacteria (*colibacillus*, *Pasteurella*, *Salmonella*) and *Mycoplasma*.

4.3 Pharmacokinetics

SPECTINOMYCIN:

After intramuscular administration, it is rapidly absorbed and reaches maximum concentrations in the blood within 20 minutes, and it is detectable for 12 hours.

It presents low penetration in the tissues and its distribution is primarily extracellular.

It is excreted by glomerular filtration and about 80% can be recovered unchanged in urine during the first 24-48 hours.

LINCOMYCIN:

It is well absorbed after intramuscular administration. It reaches a plasma peak between 2-4 hours after administration, with therapeutic concentrations persisting approximately 6-8 hours.

It is widely distributed throughout the body, crossing the placental barrier. The concentrations reached in tissues are higher than serum concentrations. It is metabolized in the liver, reaching high concentrations in the bile. Approximately 30% of the dose is excreted in urine during the first 4 hours and 14% in the feces. It is also excreted in milk.

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

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

100 ml and 250 ml translucent polypropylene vials, with bromobutyl stopper and aluminium cap with FLIP-OFF seal.

Pack sizes:

- Box with 1 vial of 100 ml
- Box with 1 vial of 250 ml
- Box with 10 vials of 100 ml
- Box with 6 vials 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.

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

Kela nv

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX for 100 ml and 250 ml vials.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SPECTOLIKEL 50/100 mg/ml solution for injection (PT)
SPECTOLIPHEN 50/100 mg/ml solution for injection (BE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Spectinomycin (as sulphate) 100 mg
Lincomycin (as hydrochloride) 50 mg

3. PACKAGE SIZE

100 ml
250 ml
10 x 100 ml
6 x 250 ml

4. TARGET SPECIES

Non-ruminating calves, sheep, pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use (i.m.)

7. WITHDRAWAL PERIODS

Withdrawal periods:

Non-ruminating calves:

Meat and offal: 23 days

Sheep:

Meat and offal: 15 days

Milk: not authorised for use in animals producing milk for human consumption.

Pigs:

Meat and offal: 14 days

8. EXPIRY DATE

Exp. {mm/yyyy}

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

Once broached, use by....

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

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

Kela nv

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 100 ml and 250 ml vial.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SPECTOLIKEL 50/100 mg/ml solution for injection (PT)
SPECTOLIPHEN 50/100 mg/ml solution for injection (BE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Spectinomycin (as sulphate) 100 mg
Lincomycin (as hydrochloride) 50 mg

3. TARGET SPECIES

Non-ruminating calves, sheep, pigs.

4. ROUTES OF ADMINISTRATION

i.m.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal periods:

Non-ruminating calves:

Meat and offal: 23 days

Sheep:

Meat and offal: 15 days

Milk: not authorised for use in animals producing milk for human consumption.

Pigs:

Meat and offal: 14 days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

7. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Kela nv

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

SPECTOLIKEL 50/100 mg/ml solution for injection for calves, sheep and pigs (PT)
SPECTOLIPHEN 50/100 mg/ml solution for injection for calves, sheep and pigs (BE)

2. Composition

Each ml contains:

Active substances:

Lincomycin.....50 mg
(equivalent to 54.47 mg of lincomycin hydrochloride (dried substance)).
Spectinomycin.....100 mg
(equivalent to 129.45 mg of spectinomycin sulphate (dried substance)).

Excipients:

Benzyl alcohol 9 mg

A colourless sterile solution.

3. Target species

Non-ruminating calves, sheep, pigs.

4. Indications for use

Treatment of infections caused by bacteria sensitive to lincomycin and/or spectinomycin.

Non- ruminating calves:

- Treatment of respiratory infections caused by bacteria sensitive to lincomycin and/or spectinomycin.

Sheep:

- Treatment of respiratory infections caused by bacteria sensitive to lincomycin and/or spectinomycin.
- Treatment of infections caused by *Mycoplasma spp.* sensitive to lincomycin and/or spectinomycin.

Pigs:

- Treatment of enteric adenomatosis (ileitis) caused by *Lawsonia intracellularis*.
- Treatment of dysentery caused by *Brachyspira hyodysenteriae*.
- Treatment of infections caused by *E. coli* sensitive to lincomycin and/or spectinomycin.
- Treatment of infections caused by *Mycoplasma spp.* sensitive to lincomycin and/or spectinomycin.
- Treatment of infectious arthritis caused by bacteria sensitive to lincomycin and/or spectinomycin.

5. Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in rabbits, hamsters, guinea pigs, chinchillas or horses as this could result in severe gastro-intestinal disturbance.

6. Special warnings

Special precautions for safe use in the target species:

The administration of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information about susceptibility of the target bacteria.

Administer with care in animals with background of allergic signs.

Do not administer higher doses than those recommended in sheep at the end of pregnancy or the beginning of lactation.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Lincomycin and spectinomycin can cause hypersensitivity (allergy) after injection, inhalation, ingestion or spillage onto skin.

Allergic reactions to these substances can be severe.

People with known hypersensitivity to these antibiotics should avoid contact with the veterinary medicinal product.

Care should be taken when handling the veterinary medicinal product to avoid any risk of exposure.

In case of exposure to the veterinary medicinal product, symptoms such as cutaneous eruption can occur. Seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of face, lips or lids or breathing difficulties are more severe signs and need urgent medical care.

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

There are no studies carried out in pregnant and lactating females. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Concomitant administration with general anaesthetics or neuromuscular blocking agents could potentiate the neuromuscular blocking.

Overdose:

None known

Major incompatibilities:

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

7. Adverse events

Non-ruminating calves, sheep, pigs.

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Soft stool ¹ Injection site reaction ² Neuromuscular disorder ³
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¹ Softening of stools can be observed. It is normally transient and recovers within few days without treatment.

² The administration of this veterinary medicinal product may cause local discomfort upon injection.

³ Lincosamides and aminoglycosides can induce neuromuscular blocking.

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 (i.m.)

Non-ruminating calves:

5 mg of lincomycin and 10 mg spectinomycin per kg bw (corresponding to 1 ml of the veterinary medicinal product/10 kg bw) intramuscularly, twice daily for the first day followed by once daily for 3-5 days.

Sheep:

5 mg of lincomycin and 10 mg spectinomycin per kg bw (corresponding to 1 ml of the veterinary medicinal product/10 kg bw) intramuscularly, once daily for 3-5 days.

Pigs:

5 mg of lincomycin and 10 mg spectinomycin per kg bw (corresponding to 1 ml of the veterinary medicinal product/10 kg bw) intramuscularly, to be repeated, if necessary, 24 hours later and for 5 days maximum.

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

9. Advice on correct administration

Do not puncture the stopper more than 30 times. Otherwise, automatic syringe equipment, or a suitable draw-off needle, should be used to avoid excessive puncturing of the closure.

10. Withdrawal periods

Non-ruminating calves:

Meat and offal: 23 days

Sheep:

Meat and offal: 15 days

Milk: not authorised for use in animals producing milk for human consumption.

Pigs:

Meat and offal: 14 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.

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

12. Special precautions for disposal

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

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

100 ml and 250 ml translucent polypropylene vials, with bromobutyl stopper and aluminium cap with FLIP-OFF seal.

Pack sizes:

- Box with 1 vial of 100 ml
- Box with 1 vial of 250 ml
- Box with 10 vials of 100 ml
- Box with 6 vials 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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:

Kela nv
Sint Lenaartseweg 48
2320 Hoogstraten
BELGIUM
Tel: +32 3 340 04 11
E-mail: info@kela.health

Manufacturer responsible for batch release:

S.P. VETERINARIA, S.A.
Ctra. Reus a Vinyols, Km 4,1
43330 – RIUDOMS
TARRAGONA, ESPAÑA

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information