Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Spirovet 600 000 IU/ml solution for injection for cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :
Active substance:
Spiramycin..... 600 000 IU

Excipient:
Benzyl alcohol (E 1519)..... 41.6 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
Clear, yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Treatment of acute clinical mastitis in lactating cows caused by *Staphylococcus aureus* strains sensitive to spiramycin.

Treatment of respiratory infections caused by *Pasteurella multocida* and *Mannheimia haemolytica.*

4.3 Contraindications

Do not use in cases of 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 administer more than 15 ml per injection site.
Use of the 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 (regional, farm level) epidemiological information about susceptibility of the target bacteria. Use of the product deviating from the instructions given in the product information may increase the prevalence of bacteria resistant to spiramycin. Official, national and regional antimicrobial policies should be taken into account when the product is used.
Mastitis caused by *S. aureus* should be treated once clinical signs are observed.
Only acute cases of mastitis caused by *S. aureus* with clinical signs observed for less than 24 h should be treated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product may cause allergic reactions in those that are sensitive.
People with known hypersensitivity to spiramycin and/or to other macrolides or to the components of the formulation should avoid contact with the product.
Care should be taken when handling the product to avoid self-injection. In case of accidental self-injection, seek medical advice, and show the package leaflet.
The product may cause irritation if it comes into contact with skin or eyes.
In case of accidental eye exposure, wash with plenty of water.
In case of accidental contact with skin, rinse immediately with water.
Wash hands and exposed skin after use.

4.6 Adverse reactions (frequency and seriousness)

Macroscopic lesions at the injection site may occur after the treatment in cattle. These lesions may still be present 42 days after injection.
Hypersalivation may occur 3 hours after the treatment in cattle.

4.7 Use during pregnancy, lactation or lay

No teratogenicity has been reported in mice. Embryotoxicity was observed in rabbits at maternotoxic oral doses. The safety of the product has not been assessed in cows during pregnancy and lactation. However, the use of the product during pregnancy and lactation should not raise toxicological concerns.
Laboratory studies in dogs and rats have shown evidence of effects on spermatogenesis at very high dosages 2050000 IU/kg body-weight per day for 56 days.
The safety of the product has not been established in male breeding animals. Use in these animals only accordingly 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

Intramuscular use.
Bodyweight should be determined as accurately as possible to avoid underdosing.

Mastitis: 30 000 IU of spiramycin per kg bodyweight (i.e. 5 ml of product per 100 kg bodyweight) twice at 24h of interval.
Respiratory infections: 100 000 IU of spiramycin per kg bodyweight (i.e. 5 ml of product per 30 kg bodyweight) twice at 48h of interval.
Do not administer more than 15 ml per injection site.

If this means that the dose must be divided into two injections, then injections should be administered on opposite sides of the neck. If more than two injections are needed, a distance of at least 15 cm should be maintained between injections given on the same side of the neck.
For the second dose (after 24 h or 48 h) the same practice should be followed, ensuring that a distance of at least 15 cm is maintained between all injections administered as part of the treatment. This procedure is necessary so that individual injection sites are kept apart. Failure to follow these instructions may result in residues above the established maximum residue limit of 200 µg/kg for muscle.

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

The spiramycin toxicity is very low and an overdosage does not induce toxic effects.

4.11 Withdrawal Period(s)

Mastitis (30 000 IU of spiramycin per kg bodyweight (i.e. 5 ml of product per 100 kg bodyweight) twice at 24h of interval)
Meat and offal: 75 days
Milk: 13.5 days

Respiratory infections (100 000 IU of spiramycin per kg bodyweight (i.e. 5 ml of product per 30 kg bodyweight) twice at 48 h of interval)
Meat and offal: 75 days
Milk: In case of treatment at the dose required for respiratory diseases, the product is not authorised for use in animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use, macrolide
ATCvet code: QJ01FA02

5.1 Pharmacodynamic properties

Spiramycin acts on bacterial protein synthesis by binding to the 50S ribosomal subunits, inhibiting the translocation step. Spiramycin is able to reach so high tissular concentrations that it succeeds in penetrating into the cells to bind the 50S ribosomal subunits.
Spiramycin is an antibiotic exerting bacteriostatic action against *Mycoplasma*, Gram negative and Gram positive bacteria.

Spiramycin is active against *Staphylococcus aureus, Mannheimia haemolytica* and *Pasteurella multocida.*

The following Minimum Inhibitory Concentrations (MIC) have been determined for spiramycin in European isolates collected from diseased animals between 2007 to 2012:

Bacteria species	**Origin**	**No. of strains**	**MIC of spiramycin (µg/mL)**		
			Range	**MIC_{50}**	**MIC_{90}**
Pasteurella multocida	Cattle	129	1 - ≥ 512	16	32
Mannheimia haemolytica	Cattle	149	4 - 512	64	128
Staphylococcus aureus	Cattle	211	1 - ≥64	4	8

5.2 Pharmacokinetic properties

Following intramuscular injection, spiramycin is rapidly absorbed and maximal plasma concentrations are reached within 3 hours. Spiramycin is a weak base, not ionized and liposoluble which crosses easily cellular membranes by passive diffusion. Spiramycin is weakly bound to plasma proteins. Its tissue distribution is extensive, with high concentrations particularly in bronchial secretions, lung parenchyma, alveolar macrophages, udders and milk.
Spiramycin is metabolised in the liver, its primary metabolite, neospiramycin, possesses antimicrobial activity.
Spiramycin is eliminated primarily by biliary excretion.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E 1519)
Dimethylacetamide
Water for injections.

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

6.4 Special precautions for storage

None.

6.5 Nature and composition of immediate packaging

Nature of container
- Colourless Type I glass vial
- Translucent multi-layer plastic vial - polypropylene/ethylene vinyl alcohol (EVOH)/polypropylene vial
- Chlorobutyl rubber stopper
- Aluminum and plastic flip off capsule

Pack sizes:
Box containing 1 glass vial of 50 ml
Box containing 1 glass vial of 100 ml
Box containing 1 glass vial of 250 ml
Box containing 1 plastic vial of 50 ml
Box containing 1 plastic vial of 100 ml
Box containing 1 plastic vial of 250 ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

Ceva Sante Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10815/021/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th November 2012

Date of last renewal: 2nd December 2016

10 DATE OF REVISION OF THE TEXT

December 2016