



SPIROVET[®]

Product information

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These pages are general information pages. No guarantee is given as to the completeness of the information contained or its compliance with national regulatory requirements. Users should consult the local site of their countries to obtain information that complies with applicable national regulations.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spirovet.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 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. « List of excipients».

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1 | Target species

Cattle.

4.2 | Indications for use, specifying the target species

Cattle:

Treatment of acute clinical and subclinical 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 animals known for their hypersensitivity to spiramycin.

4.4 | Special warnings for each target species

In cattle, do not administer more than 15 ml per injection site.

4.5 | Special precautions for use

i : 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.

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

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.

People with known hypersensitivity to spiramycin and/or to other macrolides or to the components of the formulation should avoid contact with the product.

Wash hands after handling the product.

In case of accidental eye exposure, wash with plenty of water.

iii : Other precautions

None.

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.

4.7 | Use during pregnancy, lactation or lay

No teratogenic effect has been reported in studies carried out on mice. Embryotoxic effects have been observed on rabbits but at maternotoxic oral doses. The safety of the product has not been established in cow and sow during pregnancy and lactation. However, the use during pregnancy and lactation does not pose any particular problem.

Laboratory studies in dogs and rats have shown evidence of effects on spermatogenesis.

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

See chapter “Adverse reactions (frequency and seriousness)”

4.11 | Withdrawal period(s)

Mastitis

Meat and offal: 75 days

Milk: 13.5 days

Respiratory infections:

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 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 *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	Nb of strains	MIC of ceftiofur (µg/mL)		
			Range	MIC ₅₀	MIC ₉₀
<i>Pasteurella multocida</i>	Cattle	129	1 - ≥512	16	32
<i>Mannheimia haemolytica</i>	Cattle	149	4 - 512	64	128
<i>Staphylococcus aureus</i>	Cattle	211	1 - ≥64	4	8

5.2 | Pharmacokinetic particulars

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 injection.

6.2 | Incompatibilities

None.

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

To store at temperature not more than 25°C.

6.5 | Nature and composition of immediate packaging

Type I glass vial

Chlorobutyl rubber stopper

Aluminum and plastic flip off capsule

Multi-layer plastic vial - polypropylene/ethylene vinyl alcohol (EVOH)/polypropylene vial

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.