

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Spectam Injectable 10 % w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Spectinomycin (as dihydrochloride pentahydrate)	100 mg
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Excipients

Benzyl alcohol	9 mg
Sodium Metabisulphate	0.5 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Bovine animals.

4.2 Indications for use, specifying the target species

For the treatment of respiratory disease due to infection with bacteria sensitive to spectinomycin.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not administer by the intravenous route.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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.

Special precautions to be taken by the person administering the product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable as the product is intended only for use in calves.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Administer by intramuscular injection.

Calves: 10 ml per 50 kg bodyweight, (equivalent to 20 mg Spectinomycin per kg) once daily for a maximum of 5 days. To ensure a correct dosage, body weight should be determined as accurately as possible.

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

Tolerance studies at 20 mg/kg given daily for 5 days resulted in no adverse effects.

4.11 Withdrawal period(s)

Meat and offal: 32 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, spectinomycin.

ATCvet code QJ01XX04

5.1 Pharmacodynamic properties

Spectinomycin is an antibiotic which has much in common with the aminoglycosides. It has been shown by in-vitro tests to be effective against a range of gram-negative and gram-positive bacteria. However, its spectrum of action is for gram-negative bacteria. It is more bacteriostatic than bactericidal. The mechanism of action is by inhibition of protein synthesis.

5.2 Pharmacokinetic particulars

Spectinomycin is almost totally eliminated by renal glomerular filtration with 75% or more cleared in 4 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol Sodium Metabisulphite

Sodium Citrate

Citric Acid

Water for Injection

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life following first opening of the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

Pack size: 100 ml.

Container: colourless glass Type II vials.

Closure: Rubber chlorobutyl bung with aluminium overseal.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA10815/060/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988

Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

March 2019