

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Spectam Soluble Oral Powder 50 % w/w.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100g contains :

Active substance

Spectinomycin	50.00 g
(as spectinomycin dihydrochloride pentahydrate)	

Excipients

Citric acid	
Sodium citrate to	100.00 g

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.
Pre-ruminant calves.

4.2 Indications for use, specifying the target species

For the treatment of enteric infection in pigs and pre ruminant calves caused by organisms sensitive to spectinomycin. In vitro, Spectinomycin is effective against the following organisms: *Escherichia coli*, *Pasturella spp.*, *Salmonella spp.*, *Staphylococcus spp.* and *Streptococcus spp.*

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

When Spectam Soluble is being administered in the drinking water ensure no other sources of water are available. The watering system must be clean and in good working order to ensure accurate dosing.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For pre ruminant calves: 1 gram Spectam soluble (500mg spectinomycin activity) per 50 kg bodyweight given twice daily for three to five days. This can be given in food, water or as a drench.

For piglets: 1 gram Spectam soluble to every 2 litres of drinking water for three to five days.

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

Because the product is so poorly absorbed from the alimentary canal, it is difficult to overdose.

4.11 Withdrawal Period(s)

Calves intended for human consumption should not be slaughtered until 10 days following the last treatment.

Pigs intended for human consumption should not be slaughtered until 12 days following the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Spectinomycin has been shown to be produced by 2 fungi, *Streptomyces flavopersicus* and *Streptomyces spectabilis*. It has much in common with the aminoglycosides.

In-vitro tests have shown spectinomycin to be effective against a range of gram-negative and gram-positive bacteria although in the field its spectrum of action is for gram-negative bacteria.

Studies on the minimum inhibitory concentration with bacterial strains collected in the UK and Ireland have shown that the antibiotic has the following in-vitro efficacy ranges:

<u>Organism</u>	<u>Range mcg activity/ml</u>
E. coli	0.78 - 100
Salmonella	3.12 - 200

It has been demonstrated that spectinomycin is more bacteriostatic than bactericidal. The mechanism of action appears to be by inhibition of protein synthesis.

Spectinomycin is poorly absorbed from the alimentary canal. In the blood, protein binding is low at less than 10%. It is almost totally eliminated by renal glomerular filtration with 75% or more cleared in 4 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid

Sodium Citrate

6.2 Incompatibilities

None known.

6.3 Shelf-life

The shelf life expiry date for this product shall not exceed 4 years from the date of its manufacture. The product, after dissolution in drinking water, remains stable for up to 5 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Pack
Sizes: 1 g and 100 g sachet

250 g polythene container.

Container: Thermofusing unit with 4 layers: white kraft, polyethylene, aluminium, polyethylene.

High density polyethylene box

Contents: White soluble powder

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

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 Animal Health Limited
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UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10995/005/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01st October 2003

10 DATE OF REVISION OF THE TEXT

10th November 2011