

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF VETERINARY MEDICINAL PRODUCT**

Spectam Injectable 10% w/v solution for injection

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Active substance:	% w/v
Spectinomycin (as spectinomycin dihydrochloride pentahydrate)	10.00
Excipients:	
Benzyl alcohol	0.90 (as preservative)
Sodium metabisulfite	0.055 (as antioxidant)

For a full list of excipients please see section 6.1

### **3. PHARMACEUTICAL FORM**

Solution for injection.  
Sterile, pale yellow, aqueous solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Calves

#### **4.2 Indications for use**

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

#### **4.3 Contra-indications**

None.

#### **4.4 Special warnings for each target species**

None.

#### **4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals**

i. Special precautions for use in animals:

It is prudent to reserve the use of spectinomycin for clinical conditions which have responded poorly to other classes of antimicrobials.

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

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

Persons known to be hypersensitive (allergic) to spectinomycin should not handle this product.

Care should be taken to avoid accidental self-injection. In case of accidental injection seek medical advice.

Avoid contact with skin and eyes. Wash any splashes off immediately with plenty of water. Wash hands thoroughly after use.

#### **4.6 Adverse reactions (frequency and seriousness)**

Spectinomycin is an aminocyclitol antibiotic with low toxicity.

#### **4.7 Use during pregnancy, lactation or lay**

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

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None reported.

#### **4.9 Amounts to be administered and administration route**

By intramuscular injection.

Calves: 20-30 mg/kg bodyweight per a day (equivalent to 10-15 ml per 50 Kg bodyweight), once daily for a maximum of 5 days.

#### **4.10 Overdose (Symptoms, emergency procedures, antidotes)**

Spectinomycin is of low order toxicity compared with aminoglycoside antibiotics.

#### **4.11 Withdrawal periods**

Calves must not be slaughtered for human consumption during treatment.

Calves may be slaughtered for human consumption only after 32 days from the last treatment.

### **5. PHARMACOLOGICAL PROPERTIES**

**ATC Vet Code:** QJ01XX04

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.

Spectinomycin is absorbed rapidly after intramuscular administration and almost totally eliminated by renal glomerular filtration with 75% or more cleared in 4 hours. Its distribution is largely extracellular and metabolism is limited.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Benzyl alcohol  
Sodium metabisulfite  
Sodium citrate  
Citric acid (for pH adjustment)  
Water for injection

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.  
Shelf life after first opening the immediate packaging: 28 days.

### **6.4 Special precautions for storage**

Do not store above 25°C.

Protect from light.

Following the withdrawal of the first dose, use the product within 28 days.  
Discard any unused material.

### **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 medicinal product or waste materials if any**

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 Animal Health Ltd  
Explorer House  
Mercury Park  
Wycombe Lane  
Wooburn Green  
High Wycombe  
Buckinghamshire  
HP10 0HH  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER**

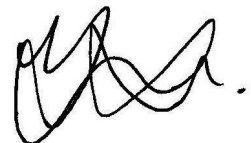
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**9. DATE OF FIRST AUTHORISATION**

31 March 1995

**10. DATE OF REVISION OF THE TEXT**

October 2022

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 06 October 2022