

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Spectam Scour Halt Oral Solution 50 mg/ml.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml:

**Active substance:**

Spectinomycin  
(as spectinomycin dihydrochloride pentahydrate) 50.0 mg

**Excipients:**

Tartrazine (E102) 0.60 mg

For a full list of excipients see section 6.1.

### 3 PHARMACEUTICAL FORM

Oral solution.

### 4 CLINICAL PARTICULARS

#### 4.1 Target Species

Pigs (piglets).  
Sheep (lambs).

#### 4.2 Indications for use, specifying the target species

- a) For the treatment of enteritis caused by strains of *Escherichia coli* sensitive to spectinomycin in piglets.
- b) For the prevention of bacterial neonatal disease (e.g. watery mouth disease) in lambs which are at risk of colostrum deprivation.

#### 4.3 Contraindications

Known hypersensitivity to the active ingredient.

Do not use in pigs over 4 weeks of age or over 7kg bodyweight.

#### 4.4 Special warnings for each target species

None known.

## **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.

Ensure that the pump and plastic extension tube are full prior to treatment. When not in use, the dosage pump and extension tube must be removed from the bottle and rinsed prior to storage.

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

None known.

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

Not 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**

By oral administration.

To ensure a correct dosage, body weight of birds to be treated should be determined as accurately as possible.

Piglets: Piglets under 4.5 kg (10 lb) - 1 pump (1 ml) twice daily. Piglets between 4.5 kg (10 lb) and 7.0 kg (15 lb) - 2 pumps (2 ml) twice daily. Treatment may be continued twice daily for 3-5 days.

Lambs: 1 pump (1 ml) once only as soon as possible after birth and within 48 hours of birth.

Insert the doser in the bottle and push the piece of clear plastic tubing over the end of the pump spout. Press the plunger a few times to fill both the pump and plastic extension tube with medication.

The preparation should be administered well back on the tongue. Each pump of the plunger delivers 1 ml of solution containing 50 mg of spectinomycin. When not in use, remove the dosing pump from the bottle. Place the clear plastic tube in the neck of the bottle and press the plunger a few times to return any medication in the pump to the bottle. Before storing for future use, always rinse out the doser with water to prevent the pump parts from sticking.

#### **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.

The symptoms of overdosage in piglets and lambs are not known. There is no known antidote to overdosage.

#### 4.11 Withdrawal Period(s)

Meat and offal:

Pigs: 12 days

Lambs: 10 days

### 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, spectinomycin.

ATCvet code QJ01XX04

#### 5.1 Pharmacodynamic 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.

#### 5.2 Pharmacokinetic properties

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

Benzoic Acid  
 Tartrazine (E102)  
 Hypromellose  
 Purified Water

#### 6.2 Incompatibilities

None known.

#### 6.3 Shelf-life

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

## **6.4 Special precautions for storage**

Do not store above 25°C.

## **6.5 Nature and composition of immediate packaging**

Container: White high density polyethylene.  
Stopper: White Polypropylene with expanded polyethylene seal.  
Plunger device: Polypropylene dip tube  
Contents: 100 ml.

## **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  
Unit 3, Anglo Office Park  
White Lion Road  
Amersham, Bucks  
HP7 9FB  
UK

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10995/004/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

30<sup>th</sup> September 2008

## **10 DATE OF REVISION OF THE TEXT**

10th November 2011