SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spectam Scour Halt oral solution 50 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:	**per 100ml**
Spectinomycin (as spectinomycin dihydrochloride pentahydrate)	5.00g
Other ingredients:	
Benzoic acid	0.10 g
Tartzine (E102)	0.06 g

3. PHARMACEUTICAL FORM

Oral solution.
A yellow viscous aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (piglets)
Sheep (lambs)

4.2 Indications for use

a) For the treatment and control 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 Contra-indications

Known hypersensitivity to the active ingredient.
Do not use in pigs over 4 weeks of age or over 7 kg bodyweight.
Use with caution in animals suffering from renal damage

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 the animals,

i. 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.

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

Do not handle in case of known hypersensivity to spectinomycin.
In case of accidental splashing on to the skin or eyes, wash the affected area with plenty of clean running water.
Wash hands thoroughly after use.

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 reported

4.9 Amounts to be administered and administration route

By oral administration.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

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.
If pigs do not improve within 48 hours, re-diagnosis is suggested

Lambs: 1 pump (1 ml) once only as soon as possible after 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)

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 periods

Animals must not be slaughtered for human consumption during treatment.

Pigs may be slaughtered for human consumption only after 12 days from the last treatment.

Lambs may be slaughtered for human consumption only after 10 days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Other antibacterials

ATC Vet Code: QJ01XX04

Spectinomycin is an aminocyclitol antimicrobial and has been shown to be produced by two kinds of fungi, *Streptomyces flavopersicus* and *Streptomyces spectabilis*. It is similar to the aminoglycosides, acting by binding to ribisomal 30s subunits of the bacteria.

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. Anaerobic organisms are generally resistant.

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

Benzoic acid
Tartrazine (E102)
Hypromellose
Purified water

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life for veterinary medicine as packaged for sale: 3 years

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Nature:

Container:	White high density polyethylene.
Stopper:	White Polypropylene.
Plunger device:	Various parts consisting of polyacetal, polyethylene, polypropylene, styrene acrylonitrile, butadiene acrylonitrile rubber.
Lubricant:	Polydimethylsiloxane.

Contents: 100 ml

6.6 Special precautions for the disposal of unused medicinal product or waste materials if any

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

7. MARKETING AUTHORISATION HOLDER

CEVA Animal Health Ltd
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8. MARKETING AUTHORISATION NUMBER

Vm 15052/4006

9. DATE OF FIRST AUTHORISATION

31st July 1997

10. DATE OF REVISION OF THE TEXT

Ocober 2022

Approved 05 October 2022