

PARTICULARS TO APPEAR ON THE OUTER BOX 100 ML**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Spectam Scour Halt oral solution 50 mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Spectinomycin (as spectinomycin dihydrochloride pentahydrate) 50 mg

Benzoic acid (preservative) 1mg

Tartzine (E102) 0.6 mg

50 mg spectinomycin activity/ml

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Piglets and lambs

6. INDICATION(S)

Lambs: for the prevention of bacterial neonatal disease (e.g. watery mouth disease) in lambs which are at risk of colostrum deprivation.

Piglets: for the treatment and control of infectious bacterial enteritis associated with *Escherichia coli*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

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

Piglets under 4.5 kg (10 lb): 1 pump (1 ml) twice daily for 3-5 days.

Piglets between 4.5 kg (10 lb) and 7.0 kg (15 lb): 2 pumps (2 ml) twice daily for 3-5 days.

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

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.

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8. WITHDRAWAL PERIODS

Lambs: 10 days from the last treatment.

Pigs: 12 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Use only in pigs under 4 weeks of age or weighing less than 7 kg. Use with caution in animals suffering from renal damage.

Do not handle in cases of known hypersensitivity to the active ingredient. For operator and other warnings, please see package leaflet.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep the container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4006

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL 100 ML**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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8. WITHDRAWAL PERIODS

Lambs: 10 days from the last treatment.

Pigs: 12 days from the last treatment.

Animals must not be slaughtered for human consumption during treatment.

9. SPECIAL WARNING(S), IF NECESSARY

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PACKAGE LEAFLET

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd Explorer House
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Piglets: for the treatment and control of infectious bacterial enteritis associated with *Escherichia coli*.

5. CONTRAINDICATIONS

Use only in pigs under 4 weeks old or weighing less than 7 kg bodyweight. Use only in lambs within 48 hours of birth.

6. ADVERSE REACTIONS

None known.

7. TARGET SPECIES

Pigs (piglets) and Sheep (lambs)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration.

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

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

Piglets under 4.5 kg (10 lb): 1 pump (1 ml) twice daily for 3-5 days.

Piglets between 4.5 kg (10 lb) and 7.0 kg (15 lb): 2 pumps (2 ml) twice daily for 3-5 days.

9. ADVICE ON CORRECT ADMINISTRATION

Ensure that the pump and plastic extension tube are full prior to treatment. 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.

When moving in between groups of lambs, depress the plunger, invert the bottle, and release the plunger to fill the pump and tubing with air. This will help to prevent leakage. When ready to recommence treatment, remember to ensure that the pump and plastic extension tube are full prior to treatment.

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment.

Lambs may be slaughtered for human consumption only after 10 days from the last treatment. Pigs may be slaughtered for human consumption only after 12 days from the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

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.

USER WARNINGS:

Do not handle in case of known hypersensitivity (allergy 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Vm 15052/4006

POM-V

To be supplied only on veterinary prescription. For animal treatment only. Keep out of sight and reach of children.

100 ml multiple-dose plastic bottle with a convenient plastic doser.

PROPERTIES

SPECTAM® SCOUR HALT is a veterinary medicinal preparation for the treatment of bacterial scours/enteritis in piglets caused by strains of *Escherichia coli* sensitive to spectinomycin and for the prevention of bacterial neonatal disease (e.g. watery mouth disease) in lambs which are at risk of colostrum deprivation.

It is presented in the form of a viscous yellow liquid contained in a plastic pump-action multidoser for oral administration. The presentation contains as active ingredient the antimicrobial, spectinomycin (as dihydrochloride pentahydrate), at the rate of 50 mg spectinomycin activity per ml. The presentation also contains Benzoic acid at 1 mg/ml. One pump of the multidoser delivers 1 ml.

Spectinomycin is an antimicrobial which belongs to the family of aminoglycosides. Its spectrum of activity is mainly for Gram-negative bacteria. The mode of action is generally regarded as being bacteriostatic, not bactericidal as with some other aminoglycosides.

Approved 05 October 2022

