

Date of Approval: JUL 29 2004

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-364

SPECMED SCOUR-CHEK
(spectinomycin dihydrochloride pentahydrate)

Oral Solution for Use in Pigs Under Four (4) Weeks of Age

For treatment and control of porcine enteric colibacillosis (scours) caused by
E. coli susceptible to spectinomycin

Sponsored by:

Cross Vetpharm Group Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-364
- b. Sponsor: Cross Vetpharm Group Ltd.
Broomhill Road
Tallaght, Dublin 24
Ireland
- Drug Labeler Code: 061623
- US Agent: Bimeda, Inc.
A Division of Cross Vetpharm Group Ltd.
Attention: Linda M. Duple
Director, North American Regulatory Affairs
2836 Dolliver Park Ave.
Lehigh, IA 50557
- c. Established Names: Spectinomycin dihydrochloride pentahydrate
- d. Proprietary Name: SPECMED SCOUR-CHEK
- e. Dosage Form: Solution
- f. How Supplied: 240 mL and 1000 mL containers
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 50 mg of spectinomycin as spectinomycin dihydrochloride pentahydrate per mL
- i. Route of Administration: Oral
- j. Species/Class: Pigs under 4 weeks of age or weighing less than 15 lbs.
- k. Recommended Dosage: Pigs under 10 lbs. – 1 pump (1 mL) twice daily.
Pigs over 10 lbs. – 2 pumps (2 mL) twice daily.
- l. Pharmacological Category: Antimicrobial
- m. Indications: For use in pigs under four (4) weeks of age for treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin.

- n. Pioneer Product: SPECTAM SCOUR-HALT; spectinomycin dihydrochloride pentahydrate; NADA 033-157; Phoenix Scientific, Inc.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guidance, revised October 9, 2002).

Based on the formulation characteristics of the generic product Cross Vetpharm Group Ltd. was granted a waiver from the requirement of an *in vivo* bioequivalence study for SPECMED SCOUR-CHEK (spectinomycin dihydrochloride pentahydrate). The generic product is administered as an oral solution, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product SPECTAM SCOUR-HALT (spectinomycin dihydrochloride pentahydrate), the subject of Phoenix Scientific, Inc. NADA 033-157, was approved on August 21, 1970.

3. HUMAN SAFETY:

• Tolerance for Residues:

The tolerances established for the pioneer product apply to the generic product. There are no tolerances listed for the pioneer product under 21 CFR 556.600.

• Withdrawal Times:

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

The withdrawal time of 21 days has been established for SPECMED SCOUR-CHEK, spectinomycin dihydrochloride pentahydrate, in pigs not over 15 lbs body weight or over 4 weeks of age (21 CFR 520.2122).

- **Regulatory Method for Residues:**

The analytical method for detection of parent spectinomycin residues in tissues utilizes an HPLC ion exchange separation with post-column derivatization and fluorescence detection.

This method is found on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal, Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that SPECMED SCOUR-CHEK, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-364:

SPECMED SCOUR-CHEK (spectinomycin dihydrochloride pentahydrate)

Container Label – 240 mL and 1000 mL

Carton Label – 240 mL

Pioneer Labeling for NADA 033-157:

SPECTAM SCOUR-HALT (spectinomycin dihydrochloride pentahydrate)

Container Label – 240 mL and 1000 mL

Carton Label – 240 mL

May 5, 2004

PANTONE 877 CVC
Metalic Silver

PANTONE 187 CVC

BLACK

INDICATIONS: For use in pigs under four (4) weeks of age for treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin.

EACH mL CONTAINS: Spectinomycin (from spectinomycin dihydrochloride pentahydrate) 50 mg

WARNING: This product is only intended for use in pigs under four (4) weeks of age or weighing less than 15 lbs.

Store at controlled room temperature, 20°-25° C (68°-77°F)

TAKE TIME  OBSERVE LABEL DIRECTIONS

Product No. 1SPE003 8SPE001

UPC 80%
0 61133 60029 1

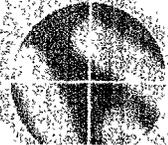
SpecMed and Scour-Chek are Trademarks of Bimeda, Inc.
(Division of Cross Valpharm Group Ltd.)

Sponsored by: Cross Valpharm Group Ltd.
Manufactured by: Bimeda-MTC Animal Health, Inc.
Cambridge, Ontario, Canada N5C 2W4

SpecMed™ Scour-Chek™ (Spectinomycin)

**ORAL SOLUTION
FOR PIG SCOURS
ANTI-INFECTIVE**

**FOR ANIMAL USE ONLY
NOT FOR HUMAN USE
KEEP OUT OF REACH
OF CHILDREN**



ANADA 200-364, Approved by FDA

**NET CONTENTS:
240 mL (8 fl oz)**

Manufactured for: Bimeda, Inc.
(Division of Cross Valpharm Group Ltd.)
Riverside, MO 64450


Bimeda

DOSE: Pigs under 10 lbs. - 1 pump (1 mL) twice daily.
Pigs over 10 lbs. - 2 pumps (2 mL) twice daily.
Each pump of the plunger delivers 1 mL of solution containing 50 mg of spectinomycin. Treatment may be continued twice daily for 3 to 5 days. If pigs do not improve within 48 hours, re-diagnosis is suggested.

DIRECTIONS FOR USE: The plastic doser supplied in each package with SpecMed™ Scour-Chek™ makes treatment easy. After inserting the doser in the bottle, screw the top on tightly to avoid spilling. Push the piece of clear plastic tubing over the end of the pump. Then press the plunger a few times to fill the pump and the clear plastic tube with medication. To administer SpecMed™ Scour-Chek™, insert the plastic tube in the pig's mouth and press the plunger to obtain the desired dose.

When not in use remove the plunger from the bottle. Put the clear plastic tube in the neck of the bottle and press the plunger a few times to remove the medication from the pump. Replace the original cap on the bottle and always rinse out the doser with water to prevent sticking.

**Do not administer within 21 days of slaughter.
Restriated Drug - Use Only As Directed (California)**

LOT:
EXP:

INDICATIONS:

For use in pigs under four (4) weeks of age for treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin.

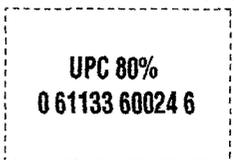
EACH mL CONTAINS:

Spectinomycin (from spectinomycin dihydrochloride pentahydrate) 50 mg

WARNING:

This product is only intended for use in pigs under four (4) weeks of age or weighing less than 15 lbs.

Store at controlled room temperature, 20°-25° C (68°-77°F)



Product No. 1SPE004 8SPE002

SpecMed and Scour-Chek are Trademarks of Bimeda, Inc. (Division of Cross Vetpharm Group Ltd.)

Sponsored by: Cross Vetpharm Group Ltd.

Manufactured by: Bimeda-MTC Animal Health Inc. Cambridge, Ontario, Canada N3C 2W4

SpecMed™ Scour-Chek™ (Spectinomycin)

**ORAL SOLUTION
FOR PIG SCOURS**

ANTI-INFECTIVE

**FOR ANIMAL USE ONLY
NOT FOR HUMAN USE
KEEP OUT OF REACH OF CHILDREN**



ANADA 200-364, Approved by FDA

**NET CONTENTS:
1000 mL (33.8 fl oz)**

Manufactured for: Bimeda, Inc.
(Division of Cross Vetpharm Group Ltd.)
Riverside, MO 64150



DOSE:

Pigs under 10 lbs. - 1 pump (1 mL) twice daily.
Pigs over 10 lbs. - 2 pumps (2 mL) twice daily.
Each pump of the plunger delivers 1 mL of solution containing 50 mg of spectinomycin. Treatment may be continued twice daily for 3 to 5 days. If pigs do not improve within 48 hours, rediagnosis is suggested.

DIRECTIONS FOR USE:

The 1000 mL bottle of SpecMed™ Scour-Chek™ should be used only to refill the 240 mL container in the following manner:

1. Remove the cap and doser from the 240 mL bottle.
2. Unscrew the cap from the 1000 mL bottle.
3. Pour, from the 1000 mL bottle, the volume desired.
4. Reinsert the doser in the 240 mL bottle and screw the top on tightly.
5. Screw the top tightly on the 1000 mL bottle.

Follow the detailed instructions for use shown on the carton containing the 240 mL bottle of SpecMed™ Scour-Chek™.

**Do not administer within 21 days of slaughter.
Restricted Drug - Use Only As Directed (California)**

LOT:
EXP:

PANTONE 877 CVC
Metallic Silver

PANTONE 187 CVC

BLACK



Bimeda, Inc.
Riverside, MO 64150

SpecMed™
Scour-Chek™
(Spectinomycin)

SpecMed™
Scour-Chek™
(Spectinomycin)

EACH mL CONTAINS:
Spectinomycin (from spectinomycin dihydrochloride pentahydrate) 50 mg
SpecMed™ Scour-Chek™ contains spectinomycin. This antibiotic is fast-acting and effective against a variety of gram-negative and gram-positive organisms. SpecMed™ Scour-Chek™ is a convenient dosage form of spectinomycin for baby pigs.

HOW SUPPLIED: SpecMed™ Scour-Chek™ is supplied in 240 mL multiple-dose plastic bottles. Each bottle is individually packed in a carton with a convenient plastic doser.

WARNING:
This product is only intended for use in pigs under four (4) weeks of age or weighing less than 15 lbs.
Do not administer within 21 days of slaughter.

DIRECTIONS FOR USE:
The plastic doser supplied in each package with SpecMed™ Scour-Chek™ makes treatment easy. After inserting the doser in the bottle, screw the top on tightly to avoid spilling. Push the piece of clear plastic tubing over the end of the pump. Then press the plunger a few times to fill the pump and the clear plastic tube with medication. To administer SpecMed™ Scour-Chek™, insert the plastic tube in the pig's mouth and press the plunger to obtain the desired dose.

When not in use, remove the plunger from the bottle. Put the clear plastic tube in the neck of the bottle and press the plunger a few times to remove the medication from the pump. Replace the original cap on the bottle and always rinse out the doser with water to prevent sticking.

SpecMed™
Scour-Chek™
(Spectinomycin)

INDICATIONS:
For use in pigs under four (4) weeks of age for treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin.

DOSE:
Pigs under 10 lbs. - 1 pump (1 mL) twice daily.
Pigs over 10 lbs. - 2 pumps (2 mL) twice daily.
Each pump of the plunger delivers 1 mL of solution containing 50 mg of spectinomycin. Treatment may be continued twice daily for 3 to 5 days. If pigs do not improve within 48 hours, re diagnosis is suggested.

Restricted Drug - Use Only As Directed (California)

Store at controlled room temperature, 20°-25° C. (68°-77° F)

ORAL SOLUTION FOR PIG SCOURS

ANTI-INFECTIVE

**FOR ANIMAL USE ONLY
NOT FOR HUMAN USE
KEEP OUT OF REACH OF CHILDREN**

ANADA 200-364, Approved by FDA

**NET CONTENTS:
240 mL (8 fl oz)**

Manufactured for: Bimeda, Inc.
(Division of Cross Velpham Group Ltd.)
Riverside, MO 64150



ORAL SOLUTION FOR PIG SCOURS

ANTI-INFECTIVE

**FOR ANIMAL USE ONLY
NOT FOR HUMAN USE
KEEP OUT OF REACH OF CHILDREN**

ANADA 200-364, Approved by FDA

**NET CONTENTS:
240 mL (8 fl oz)**

Manufactured for: Bimeda, Inc.
(Division of Cross Velpham Group Ltd.)
Riverside, MO 64150



TAKE TIME **OBSERVE LABEL INSTRUCTIONS**

SpecMed and Scour-Chek are Trademarks of Bimeda, Inc. (Division of Cross Velpham Group Ltd.)

Sponsored by: Cross Velpham Group Ltd.
Manufactured by: Bimeda-MTC Animal Health Inc.
Canning, Ontario, Canada N3C 2W4

Product No. 1SPB008 B5PE003

UPC 80%
0 61133 60029 1

INDICATIONS: For use in pigs under four (4) weeks of age for treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin.

EACH mL CONTAINS:
Spectinomycin (from spectinomycin dihydrochloride pentahydrate) 50 mg

WARNING: This product is only intended for use in pigs under four weeks of age or weighing less than 15 lbs.

Store at controlled room temperature, 20°-25°C (68°-77°F).

500027

Iss. 03-00



Manufactured By:
Phoenix Scientific, Inc.
St. Joseph, MO 64503

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™ Trademark of Meril Limited

NDC 59130-732-38

**LIQUID
SPECTAM®
SCOUR-HALT™**

(Spectinomycin)

**ORAL SOLUTION FOR PIG SCOURS
ANTI-INFECTIVE**

**FOR ANIMAL USE ONLY
NOT FOR HUMAN USE**

KEEP OUT OF REACH OF CHILDREN

NADA 033-157, Approved by FDA

NET CONTENTS: 240 mL (8 Fl Oz)

AmTech®
Group, Inc.

DOSE: Pigs under 10 lbs - 1 pump (1 mL) twice daily.
Pigs over 10 lbs - 2 pumps (2 mL) twice daily.

Each pump of the plunger delivers 1 mL of solution containing 50 mg of spectinomycin. Treatment may be continued twice daily for 3 to 5 days. If pigs do not improve within 48 hours, re-diagnosis is suggested.

ADMINISTRATION: The plastic doser supplied in each package with SPECTAM SCOUR-HALT makes treatment easy. After inserting the doser in the bottle, screw the top on tightly to avoid spilling. Push the piece of clear plastic tubing over the end of the pump. Then press the plunger a few times to fill the pump and the clear plastic tube with medication. To administer SPECTAM SCOUR-HALT, insert the plastic tube in the pig's mouth and press the plunger to obtain the desired dose.

When not in use remove the plunger from the bottle. Put the clear plastic tube in the neck of the bottle and press the plunger a few times to remove the medication from the pump. Replace the original cap on the bottle and always rinse out the doser with water to prevent sticking.

**Do not administer within 21 days of slaughter.
Restricted Drug - Use Only As Directed (California)**

Lot No. Exp. Date

INDICATIONS: For use in pigs under four (4) weeks of age for treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin.

EACH mL CONTAINS:
Spectinomycin (from spectinomycin dihydrochloride pentahydrate) 50 mg

WARNING: This product is only intended for use in pigs under four weeks of age or weighing less than 15 lbs.

Store at controlled room temperature, 20°-25°C (68°-77°F).

500027



Manufactured By:
Phoenix Scientific, Inc.
St. Joseph, MO 64503



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™ Trademark of Phoenix Scientific, Inc.

NDC 59130-732-04

**LIQUID
SPECTAM®
SCOUR-HALT™
(Spectinomycin)**

**ORAL SOLUTION FOR PIG SCOURS
ANTI-INFECTIVE**

**FOR ANIMAL USE ONLY
NOT FOR HUMAN USE
KEEP OUT OF REACH OF CHILDREN**

NADA 033-157, Approved by FDA

**NET CONTENTS:
1000 mL (33.8 fl oz)**



DOSE: Pigs under 10 lbs - 1 pump (1 mL) twice daily.
Pigs over 10 lbs - 2 pumps (2 mL) twice daily.

Each pump of the plunger delivers 1 mL of solution containing 50 mg of spectinomycin. Treatment may be continued twice daily for 3 to 5 days. If pigs do not improve within 48 hours, rediagnosis is suggested.

DIRECTIONS FOR USE: The 1000 mL bottle of SPECTAM Scour-Halt should be used only to refill the 240 mL container in the following manner.

1. Remove the cap and doser from the 240 mL bottle.
2. Unscrew the cap from the 1000 mL bottle.
3. Pour (from the 1000 mL bottle) the volume desired.
4. Reinsert the doser in the 240 mL bottle and screw the top on tightly.
5. Screw the top tightly on the 1000 mL bottle.

Follow the detailed instructions for use shown on the carton containing the 240 mL bottle of SPECTAM Scour-Halt.

Do not administer within 21 days of slaughter.

Restricted Drug - Use Only As Directed (California)

Lot No. Exp. Date

AmTech
Group, Inc.

AmTech
 NDC 59130-732-38
SPECTAM®
LIQUID
SCOUR-HALT™
 (spectinomycin)
 ORAL SOLUTION FOR
 PIG SCOURS
 NET CONTENTS: 240 mL (8 fl oz)

EACH mL CONTAINS: Spectinomycin (from spectinomycin dihydrochloride pentahydrate)..... 50 mg

SPECTAM® SCOUR-HALT™ contains spectinomycin. This antibiotic is fast-acting and effective against a variety of gram-negative and gram-positive organisms. **SPECTAM® SCOUR-HALT™** is a convenient dosage form of **SPECTAM®** for baby pigs.

HOW SUPPLIED: **SPECTAM® SCOUR-HALT™** is supplied in 240 mL multiple-dose plastic bottles. Each bottle is individually packed in a carton with a convenient plastic doser.

WARNING: This product is only intended for use in pigs under four weeks of age or weighing less than 15 lbs.

Do not administer within 21 days of slaughter.

ADMINISTRATION: The plastic doser supplied in each package with **SPECTAM® SCOUR-HALT™** makes treatment easy. After inserting the doser in the bottle, screw the top on tightly to avoid spilling. Push the piece of clear plastic tubing over the end of the pump. Then press the plunger a few times to fill the pump and the clear plastic tube with medication. To administer **SPECTAM® SCOUR-HALT™**, insert the plastic tube in the pig's mouth and press the plunger to obtain the desired dose.

When not in use remove the plunger from the bottle. Put the clear plastic tube in the neck of the bottle and press the plunger a few times to remove the medication from the pump. Replace the original cap on the bottle and always rinse out the doser with water to prevent sticking.

NDC 59130-732-38

LIQUID
SPECTAM®
SCOUR-HALT™
 (spectinomycin)

ORAL SOLUTION FOR PIG SCOURS

ANTI-INFECTIVE

FOR ANIMAL USE ONLY
 NOT FOR HUMAN USE
 KEEP OUT OF REACH OF CHILDREN

SEE SIDE PANEL FOR INDICATIONS AND DOSAGE

NADA 033-157, Approved by FDA

TAKE TIME  OBSERVE LABEL DIRECTIONS

NET CONTENTS: 240 mL (8 fl oz)

AmTech
 Group, Inc.

INDICATIONS: For use in pigs under four (4) weeks of age for the treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin.

DOSE: Pigs under 10 lbs - 1 pump (1 mL) twice daily.

Each pump of the plunger delivers 1 mL of solution containing 50 mg of spectinomycin. Treatment may be continued twice daily for 3 to 5 days. If pigs do not improve within 48 hours, re-diagnosis is suggested.

Restricted Drug - Use Only As Directed (California)

Store at controlled room temperature, 20°-25°C (68° - 77°F).

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 ™Trademark of Merial Limited

Manufactured by:
 Phoenix Scientific, Inc.
 St. Joseph, MO 64503

Lot No.

Exp. Date

500027

Iss. 7/00

NDC 59130-732-38

LIQUID
SPECTAM®
SCOUR-HALT™
 (spectinomycin)

ORAL SOLUTION FOR PIG SCOURS

ANTI-INFECTIVE

FOR ANIMAL USE ONLY
 NOT FOR HUMAN USE
 KEEP OUT OF REACH OF CHILDREN

SEE SIDE PANEL FOR INDICATIONS AND DOSAGE

NADA 033-157, Approved by FDA

TAKE TIME  OBSERVE LABEL DIRECTIONS

NET CONTENTS: 240 mL (8 fl oz)

AmTech
 Group, Inc.

NDC 59130-732-38

LIQUID
SPECTAM®
SCOUR-HALT™
 (spectinomycin)

ORAL SOLUTION FOR PIG SCOURS

NET CONTENTS: 240 mL (8 fl oz)

AmTech
 Group, Inc.

1 2 3
 4 5 6