

2006-200.394
Approval Date: NOV

FREEDOM OF INFORMATION SUMMARY

**ORIGINAL ABBREVIATED NEW ANIMAL
DRUG APPLICATION**

ANADA 200-394

**Gentamicin Piglet Injection
(gentamicin sulfate)**

**Indicated for the treatment of porcine colibacillosis caused by
strains of *E. coli* sensitive to gentamicin**

Sponsored by:

Sparhawk Laboratories, Inc.

2006-200.394

FOIS2

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number ANADA 200-394
- b. Sponsor: Sparhawk Laboratories, Inc.
12340 Santa Fe Trail Drive
Lenexa, KS 66215

Drug Labeler Code: 058005
- c. Established Name: Gentamicin sulfate
- d. Proprietary Name: Gentamicin Piglet Injection
- e. Dosage Form: Injection
- f. How Supplied: 100 mL, 250 mL, and 500 mL multiple dose vials
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Each mL contains: gentamicin sulfate, USP equivalent to 5 mg gentamicin base
- i. Route of Administration: Intramuscular
- j. Species/Class: Swine, piglets only up to 3 days of age
- k. Recommended Dosage: 1 mL per piglet
- l. Pharmacological Category: Antimicrobial
- m. Indications: For the treatment of porcine colibacillosis caused by strains of *E. coli* sensitive to gentamicin
- n. Pioneer Product: GARACIN Piglet Injection; Gentamicin sulfate; NADA 103-037; Schering-Plough Animal Health Corp.

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 is required to show that 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 Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Sparhawk Laboratories, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Gentamicin (gentamicin sulfate) Piglet Injection. The generic product is administered as an injection, contains the same active ingredients 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, GARACIN (gentamicin sulfate) Piglet Injection the subject of Schering-Plough Animal Health Corp, NADA 103-037, was approved on January 7, 1983.

3. HUMAN SAFETY:

- **Tolerances for Residues:**

The tolerance established for the pioneer product applies to the generic product. A tolerance 0.1 part per million (ppm) in muscle, 0.3 ppm in liver, and 0.4 ppm in fat and kidney is established for gentamicin residues in the uncooked edible tissues of swine under 21 CFR 556.300.

- **Withdrawal Times:**

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product (21 CFR 522.1044).

The withdrawal time is at least 40 days following treatment.

- **Regulatory Method for Residues:**

The procedure for the determination of gentamicin in tissues is a microbiological determinative procedure and an HPLC confirmatory procedure for gentamicin have been developed to assay gentamicin in kidney at 0.4 ppm. Since residues of gentamicin as the parent compound and total residues are equal, the marker (parent drug) residue concentration of 0.4 ppm in kidney corresponds to 0.4 ppm of total residue. The validated methods are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This original ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that GARACIN Piglet Injection, 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 200-394:

Product label and outsert, 100 mL package size

Product label and outsert, 250 mL package size

Product label and outsert, 500 mL package size

Pioneer Labeling for NADA 103-037:

Product label, 250 mL package size

Package insert

Product carton, 250 mL package size

For use in piglets only, up to 3 days of age.

Each mL contains: gentamicin sulfate, USP equivalent to 5 mg gentamicin base, 2 mg sodium bisulfite, 0.1 mg edetate disodium, 7.46 mg sodium acetate, 3 mg glacial acetic acid, 1.3 mg methylparaben and 0.2 mg propylparaben as preservatives, water for injection q.s.

Indications: Gentamicin Piglet Injection is recommended for the treatment of porcine colibacillosis caused by strains of *E. coli* sensitive to gentamicin.

Lot No. Exp. Date

G-6639-04
Rev. 8-05

Gentamicin Piglet Injection

(GENTAMICIN SULFATE, USP)

Piglet Injection Antibacterial

100 Doses
5mg/mL

ANADAA: 288-384 Approved by F.D.A.

NET CONTENTS: 3.4 oz (100 mL)



Dose: 1 mL per piglet, administered intramuscularly. Gentamicin Piglet Injection is not to be used more than once in each piglet.

WARNING: Piglets injected with Gentamicin Piglet Injection must not be slaughtered for food for at least 40 days following treatment.

Restricted Drug (California)—use only as directed.

Read accompanying directions carefully.

Store between 2° and 38°C (36° and 98°F)

For intramuscular use only.

ANADAA: 288-384 Approved by F.D.A.



Manufactured by
Sparhawk Laboratories, Inc.
Lenexa, KS 66215

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7	<p>Dose: 1 mL per piglet, administered intramuscularly. Gentamicin Piglet Injection is not to be used more than once in each piglet.</p> <p>WARNING: Piglets injected with Gentamicin Piglet Injection must not be slaughtered for food for at least 40 days following treatment.</p> <p>Restricted Drug (California)—use only as directed.</p> <p>Read accompanying directions carefully.</p> <p>Store between 2° and 38°C (36° and 98°F)</p> <p>For intramuscular use only.</p> <p>ANADAA: 288-384 Approved by F.D.A.</p>  <p>Manufactured by Sparhawk Laboratories, Inc. Lenexa, KS 66215</p>	<h3 style="margin: 0;">Gentamicin Piglet Injection</h3> <p style="margin: 0;">(GENTAMICIN SULFATE, USP)</p> <h3 style="margin: 0;">Piglet Injection- 5mg/mL</h3> <p style="margin: 0;">Piglet Injection Veterinary Antibacterial</p> <p style="margin: 0;">For Piglets Up to 3 days of age</p> <p style="margin: 0;">DESCRIPTION Gentamicin Piglet Injection is a sterile preparation for intramuscular administration in piglets up to 3 days of age. Each milliliter</p>	<p>contains gentamicin sulfate, USP equivalent to 5 mg gentamicin base, 2 mg sodium bisulfite, 0.1 mg edetate disodium, 7.46 mg sodium acetate, 3 mg glacial acetic acid, 1.3 mg methylparaben and 0.2 mg propylparaben as preservatives, water for injection q.s.</p> <p>WARNING: For use in piglets up to 3 days of age only. Piglets injected with Gentamicin Piglet Injection must not be slaughtered for food for at least forty (40) days following treatment. Use of more than the recommended dose will result in gentamicin tissue residues beyond forty (40) days.</p>
1	2	3	4
<p>INDICATIONS: Gentamicin Piglet Injection is recommended for the treatment of porcine colibacillosis caused by strains of <i>E. coli</i> sensitive to gentamicin.</p> <p>DOSAGE AND ADMINISTRATION: The recommended dose is 1 mL (5 mg) administered intramuscularly. Gentamicin Piglet Injection is not to be used more than once in each piglet. If piglets do not respond to treatment with Gentamicin Piglet Injection, diagnosis should be reevaluated. Clean and sterilize needles and syringes by boiling in water for 15 minutes prior to use.</p>	<p>Prior to injection, disinfect the injection site and top of the vial with a suitable disinfectant, such as 70% alcohol. Use all precautions to prevent contamination of vial contents.</p> <p>CONTRAINDICATIONS: There are no known contraindications to this drug when used as directed.</p> <p>PRECAUTIONS: Store between 2° and 30°C (36° and 86°F)</p> <p>CHEMISTRY: Gentamicin is a mixture of aminoglycoside antibiotics derived from the fermentation of <i>Micromono-</i></p>	<p><i>spora purpurea.</i> Gentamicin sulfate, USP is a mixture of sulfate salts of the antibiotics produced in this fermentation. The salts are weakly acidic and freely soluble in water. Gentamicin sulfate, USP is stable in solution for the period of time indicated on the labels by the expiration date.</p> <p>Gentamicin sulfate, USP contains not less than 500 micrograms of gentamicin base per milligram.</p> <p>HOW SUPPLIED: Gentamicin Piglet Injection, 5mg/mL is available in 100 mL, 250 mL and 500 mL multiple dose vials.</p>	5
1	4	5	6

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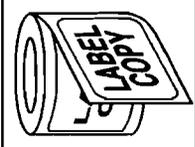
Customer: Sparhawk P.O. #: Rachel CYREL #: 33669 (In)

Customer Service: Kathy Roper • kroper@tabcoinc.com

Date 10/27/06 11/01/06 11/06/06

desc.:	Gentamicin Piglet Injection	100 mL	size:	1.875 " x 5.75 "
varnish:	lamination: <input checked="" type="checkbox"/>	colors:	black	202 red
<input type="checkbox"/> pattern			877 silver	
<input type="checkbox"/> flood				

Unwind #: 4



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OK as shown make corrections and resubmit
 OK w / corrections

Date: _____

<p>For use in piglets only, up to 3 days of age.</p> <p>Each mL contains: gentamicin sulfate, USP equivalent to 5 mg gentamicin base, 2 mg sodium bisulfite, 0.1 mg edetate disodium, 7.46 mg sodium acetate, 3 mg glacial acetic acid, 1.3 mg methylparaben and 0.2 mg propylparaben as preservatives, water for injection q.s.</p> <p>Indications: Gentamicin Piglet Injection is recommended for the treatment of porcine colibacillosis caused by strains of <i>E. coli</i> sensitive to gentamicin.</p>	<h2>Gentamicin Piglet Injection</h2> <p>(GENTAMICIN SULFATE, USP)</p> <h3>Piglet Injection</h3> <h4>Antibacterial</h4> <p>250 Doses 5mg/mL</p> <p>AMADAK: 288-284 Approved by F.D.A.</p> <p>NET CONTENTS: 8.5 oz (250 mL)</p> 	<p>Dose: 1 mL per piglet, administered intramuscularly. Gentamicin Piglet Injection is not to be used more than once in each piglet.</p> <p>WARNING: Piglets injected with Gentamicin Piglet Injection must not be slaughtered for food for at least 40 days following treatment.</p> <p>Restricted Drug (California)—use only as directed.</p> <p>Read accompanying directions carefully.</p> <p>Store between 2° and 30°C (36° and 86°F)</p> <p>For intramuscular use only.</p> <p>AMADAK: 288-284 Approved by F.D.A.</p>  <p>Manufactured by Sparhawk Laboratories, Inc. Lenexa, KS 66215</p>
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<p>Dose: 1 mL per piglet, administered intramuscularly. Gentamicin Piglet Injection is not to be used more than once in each piglet.</p> <p>WARNING: Piglets injected with Gentamicin Piglet Injection must not be slaughtered for food for at least 40 days following treatment.</p> <p>Restricted Drug (California)—use only as directed.</p> <p>Read accompanying directions carefully.</p> <p>Store between 2° and 30°C (36° and 86°F)</p> <p>For intramuscular use only.</p> <p>AMADAK: 288-284 Approved by F.D.A.</p>  <p>Manufactured by Sparhawk Laboratories, Inc. Lenexa, KS 66215</p>	<h2>Gentamicin Piglet Injection</h2> <p>(GENTAMICIN SULFATE, USP)</p> <h3>Piglet Injection- 5mg/mL</h3> <p>Piglet Injection Veterinary Antibacterial For Piglets Up to 3 days of age</p> <p>DESCRIPTION Gentamicin Piglet Injection is a sterile preparation for intramuscular administration in piglets up to 3 days of age. Each milliliter contains gentamicin sulfate, USP equivalent to 5 mg gentamicin base, 2 mg sodium bisulfite, 0.1 mg edetate disodium,</p>	<p>7.46 mg sodium acetate, 3 mg glacial acetic acid; 1.3 mg methylparaben and 0.2 mg propylparaben as preservatives, water for injection q.s.</p> <p>WARNING: For use in piglets up to 3 days of age only. Piglets injected with Gentamicin Piglet Injection must not be slaughtered for food for at least forty (40) days following treatment. Use of more than the recommended dose will result in gentamicin tissue residues beyond forty (40) days.</p> <p>INDICATIONS: Gentamicin Piglet Injection is recommended for the treatment of porcine</p>
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<p>colibacillosis caused by strains of <i>E. coli</i> sensitive to gentamicin.</p> <p>DOSAGE AND ADMINISTRATION: The recommended dose is 1 mL (5 mg) administered intramuscularly. Gentamicin Piglet Injection is not to be used more than once in each piglet. If piglets do not respond to treatment with Gentamicin Piglet Injection, diagnosis should be reevaluated. Clean and sterilize needles and syringes by boiling in water for 15 minutes prior to use. Prior to injection, disinfect the injection site and top of the vial with a suitable disinfectant, such as 70% alcohol.</p>	<p>Use all precautions to prevent contamination of vial contents.</p> <p>CONTRAINDICATIONS: There are no known contraindications to this drug when used as directed.</p> <p>PRECAUTIONS: Store between 2° and 30°C (36° and 86°F)</p> <p>CHEMISTRY: Gentamicin is a mixture of aminoglycoside antibiotics derived from the fermentation of <i>Micromonospora purpurea</i>. Gentamicin sulfate, USP is a mixture of sulfate salts of the antibiotics produced in this fermentation. The salts are</p>	<p>weakly acidic and freely soluble in water. Gentamicin sulfate, USP is stable in solution for the period of time indicated on the labels by the expiration date. Gentamicin sulfate, USP contains not less than 500 micrograms of gentamicin base per milligram.</p> <p>HOW SUPPLIED: Gentamicin Piglet Injection, 5mg/mL is available in 100 mL, 250 mL and 500 mL multiple dose vials.</p>	
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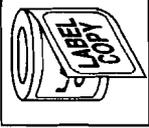
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Customer: Sparhawk P.O. #: Rachel CYREL #: 32274 (In)

Customer Service: Kathy Roper • kroper@tabcoinc.com

Date 10/27/06 11/01/06

Unwind #: 4

desc.: <u>Gentamicin Piglet Injection</u> <u>250 mL</u> size: <u>3.0</u> " x <u>6.75</u> "		
varnish: <input type="checkbox"/> pattern <input type="checkbox"/> flood	lamination: <input checked="" type="checkbox"/> colors: <u>black</u> <u>202 red</u> <u>877 silver</u>	

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OK as shown make corrections and resubmit
 OK w/ corrections Date: _____

For use in piglets only, up to 3 days of age.

Each mL contains: gentamicin sulfate, USP equivalent to 5 mg gentamicin base, 2 mg sodium bisulfite, 0.1 mg edetate disodium, 7.46 mg sodium acetate, 3 mg glacial acetic acid, 1.3 mg methylparaben and 0.2 mg propylparaben as preservatives, water for injection q.s.

Indications: Gentamicin Piglet Injection is recommended for the treatment of porcine colibacillosis caused by strains of *E. coli* sensitive to gentamicin.

Lot No. Exp. Date

G-6639-06
Rev. 8-05

Gentamicin Piglet Injection

(GENTAMICIN SULFATE, USP)

Piglet Injection Antibacterial

**500 Doses
5mg/mL**

ANADAP: 288-294 Approved by F.D.A.

NET CONTENTS: 17 oz (500 mL)



Dose: 1 mL per piglet, administered intramuscularly. Gentamicin Piglet Injection is not to be used more than once in each piglet.

WARNING: Piglets injected with Gentamicin Piglet Injection must not be slaughtered for food for at least 40 days following treatment.

Restricted Drug (California)—use only as directed.

Read accompanying directions carefully.

Store between 2° and 30°C (36° and 86°F)

For intramuscular use only.

ANADAP: 288-294 Approved by F.D.A.



Manufactured by Sparhawk Laboratories, Inc. Lenexa, KS 66215

<p>Dose: 1 mL per piglet, administered intramuscularly. Gentamicin Piglet Injection is not to be used more than once in each piglet.</p> <p>WARNING: Piglets injected with Gentamicin Piglet Injection must not be slaughtered for food for at least 40 days following treatment.</p> <p>Restricted Drug (California)—use only as directed.</p> <p>Read accompanying directions carefully.</p> <p>Store between 2° and 30°C (36° and 86°F)</p> <p>For intramuscular use only.</p> <p style="text-align: center;">ANADAP: 288-294 Approved by F.D.A.</p> <div style="text-align: center;">  <p style="font-size: 8px;">Manufactured by Sparhawk Laboratories, Inc. Lenexa, KS 66215</p> </div> <p style="text-align: center;">7</p>	<h2 style="margin: 0;">Gentamicin Piglet Injection</h2> <p style="margin: 0;">(GENTAMICIN SULFATE, USP)</p> <h3 style="margin: 0;">Piglet Injection- 5mg/mL</h3> <p style="margin: 0;">Piglet Injection Veterinary Antibacterial</p> <p style="margin: 0;">For Piglets Up to 3 days of age</p> <p>DESCRIPTION Gentamicin Piglet Injection is a sterile preparation for intramuscular administration in piglets up to 3 days of age. Each milliliter contains gentamicin sulfate, USP equivalent to 5 mg gentamicin base, 2 mg sodium bisulfite, 0.1 mg edetate disodium,</p>	<p>7.46 mg sodium acetate, 3 mg glacial acetic acid, 1.3 mg methylparaben and 0.2 mg propylparaben as preservatives, water for injection q.s.</p> <p>WARNING: For use in piglets up to 3 days of age only. Piglets injected with Gentamicin Piglet Injection must not be slaughtered for food for at least forty (40) days following treatment. Use of more than the recommended dose will result in gentamicin tissue residues beyond forty (40) days.</p> <p>INDICATIONS: Gentamicin Piglet Injection is recommended for the treatment of porcine</p> <p style="text-align: center;">2</p>
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<p>colibacillosis caused by strains of <i>E. coli</i> sensitive to gentamicin.</p> <p>DOSAGE AND ADMINISTRATION: The recommended dose is 1 mL (5 mg) administered intramuscularly. Gentamicin Piglet Injection is not to be used more than once in each piglet. If piglets do not respond to treatment with Gentamicin Piglet Injection, diagnosis should be reevaluated. Clean and sterilize needles and syringes by boiling in water for 15 minutes prior to use. Prior to injection, disinfect the injection site and top of the vial with a suitable disinfectant, such as 70% alcohol.</p> <p style="text-align: center;">3</p>	<p>Use all precautions to prevent contamination of vial contents.</p> <p>CONTRAINDICATIONS: There are no known contraindications to this drug when used as directed.</p> <p>PRECAUTIONS: Store between 2° and 30°C (36° and 86°F)</p> <p>CHEMISTRY: Gentamicin is a mixture of aminoglycoside antibiotics derived from the fermentation of <i>Micromonospora purpurea</i>. Gentamicin sulfate, USP is a mixture of sulfate salts of the antibiotics produced in this fermentation. The salts are</p> <p style="text-align: center;">4</p>	<p>weakly acidic and freely soluble in water. Gentamicin sulfate, USP is stable in solution for the period of time indicated on the labels by the expiration date. Gentamicin sulfate, USP contains not less than 500 micrograms of gentamicin base per milligram.</p> <p>HOW SUPPLIED: Gentamicin Piglet Injection, 5mg/mL is available in 100 mL, 250 mL and 500 mL multiple dose vials.</p> <p style="text-align: center;">5</p>
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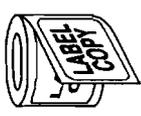
Customer: Sparhawk P.O. #: Rachel CYREL #: 33668 (In)

Customer Service: Kathy Roper • kroper@tabcoinc.com

Date 10/27/06 11/01/06

desc.:	Gentamicin Piglet Injection	500 mL	size:	3.0	" x	6.75	"
varnish:	lamination: <input checked="" type="checkbox"/>	colors:	black	202 red	877 silver		
<input type="checkbox"/> pattern							
<input type="checkbox"/> flood							

Unwind #: 4



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 OK w/ corrections

Approved by: _____ Date: _____

For use in piglets up to 3 days of age only.

Each mL contains: gentamicin sulfate, USP equivalent to 5 mg gentamicin base, 2 mg sodium bisulfite, 0.1 mg edetate disodium, 7.46 mg sodium acetate, 3 mg glacial acetic acid; 1.3 mg methylparaben and 0.2 mg propylparaben as preservatives, and water for injection q.s.

Indications: GARACIN Piglet Injection is recommended for the treatment of porcine colibacillosis caused by strains of *E. coli* sensitive to gentamicin.



The image shows the packaging label for Garacin Piglet Injection. At the top left is the Schering-Plough logo. Below it, the text reads: "Antibacterial", "NADA #103-037, Approved by FDA", and "8.5 fl. oz. (250 mL)". The central part of the label features a silhouette of a piglet and the product name "Garacin® (GENTAMICIN SULFATE, USP) Piglet Injection". To the right of the piglet is the text "Sterile" and "250 Doses 5 mg/mL". At the bottom left, it says "Schering-Plough Animal Health".

Dose: 1 mL per piglet, administered intramuscularly. GARACIN Piglet Injection is not to be used more than once in each piglet.

Warning: Piglets injected with GARACIN Piglet Injection must not be slaughtered for food for at least 40 days following treatment.

Restricted Drug (California) – use only as directed.

Read accompanying directions carefully.

Store between 2° and 30°C (36° and 86°F). For intramuscular use only.

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12600577 Rev. 1/99

LOT

EXP

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NADA #103-037, Approved by FDA.

**PRODUCT
INFORMATION**

Garacin®
(GENTAMICIN SULFATE, USP)

**Piglet Injection—5 mg/mL
Veterinary
Antibacterial
For Piglets Up to 3 Days of Age**

DESCRIPTION GARACIN Piglet Injection is a sterile preparation for intramuscular administration in piglets up to 3 days of age. Each milliliter contains gentamicin sulfate, USP equivalent to 5 mg gentamicin base, 2 mg sodium bisulfite, 0.1 mg edetate disodium, 7.46 mg sodium acetate, 3 mg glacial acetic acid; 1.3 mg methylparaben and 0.2 mg propylparaben as preservatives, and water for injection q.s.

INDICATIONS GARACIN Piglet Injection is recommended for the treatment of porcine colibacillosis caused by strains of *E. Coli* sensitive to gentamicin.

CONTRAINDICATIONS There are no known contraindications to this drug when used as directed.

WARNING For use in piglets up to 3 days of age only. Piglets injected with GARACIN Piglet Injection must not be slaughtered for food for at least forty (40) days following treatment. Use of more than the recommended dose will result in gentamicin tissue residues beyond forty (40) days.

DOSAGE AND ADMINISTRATION The recommended dose is 1 mL (5 mg) administered intramuscularly. GARACIN Piglet Injection is not to be used more than once in each piglet. If piglets do not respond to treatment with GARACIN Piglet Injection, diagnosis should be re-evaluated.

Clean and sterilize needles and syringes by boiling in water for 15 minutes prior to use. Prior to injection,

disinfect the injection site and top of the vial with a suitable disinfectant, such as 70% alcohol.

Use all precautions to prevent contamination of the vial contents.

CHEMISTRY Gentamicin is a mixture of aminoglycoside antibiotics derived from the fermentation of *Micromonospora purpurea*. Gentamicin sulfate, USP is a mixture of sulfate salts of the antibiotics produced in this fermentation. The salts are weakly acidic and freely soluble in water. Gentamicin sulfate, USP is stable in solution for the period of time indicated on the labels by the expiration date.

Gentamicin sulfate, USP contains not less than 500 micrograms of gentamicin base per milligram.

PRECAUTIONS Store between 2° and 30°C (36° and 86°F).

Restricted Drug (California)—Use only as directed.

HOW SUPPLIED GARACIN Piglet Injection, 5 mg/mL is available in 250 mL multiple-dose vials.

January 1999

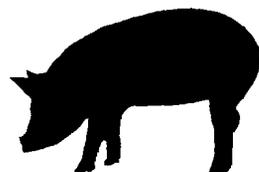
Schering-Plough Animal Health Corp.,
Union, NJ 07083

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250 Doses
5 mg/mL

Sterile

NDC 0061-0220-03



Garacin[®]
(GENTAMICIN SULFATE, USP)

Piglet
Injection
Veterinary
Antibacterial

**For piglets up to
3 days of age.**

Garacin[®]
(GENTAMICIN SULFATE, USP)

Piglet
Injection
Veterinary
Antibacterial

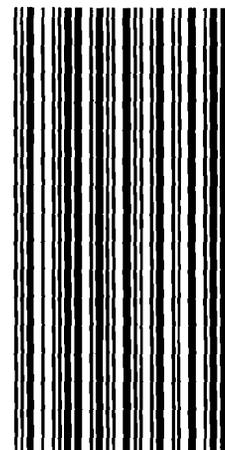
NADA #103-037, Approved by FDA.

8.5 fl. oz. (250 mL)



Schering-Plough
Animal Health

DIE 2085



Garacin®

(GENTAMICIN SULFATE, USP)

Piglet
Injection
Veterinary
Antibacterial

For piglets up to
3 days of age.



N 0061-0220-03 5



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For use in piglets up to 3 days of age.

EACH mL CONTAINS: gentamicin sulfate, USP equivalent to 5 mg gentamicin base, 2 mg sodium bisulfite, 0.1 mg edetate disodium, 7.46 mg sodium acetate, 3 mg glacial acetic acid; 1.3 mg methylparaben and 0.2 mg propylparaben as preservatives, and water for injection q.s.

INDICATIONS: GARACIN Piglet Injection is recommended for the treatment of porcine colibacillosis caused by strains of *E. coli* sensitive to gentamicin.

DOSE: 1 mL per piglet, administered intramuscularly. GARACIN Piglet Injection is not to be used more than once in each piglet.

WARNING: Piglets injected with GARACIN Piglet Injection must not be slaughtered for food for at least 40 days following treatment.

Restricted Drug (California)—Use only as directed.

Read accompanying directions carefully.

Store between 2° and 30°C (36° and 86°F).

For intramuscular use only.

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Garacin®

(GENTAMICIN SULFATE, USP)

Piglet Injection
Veterinary
Antibacterial