

GENTAMICIN PIGLET - gentamicin sulfate injection
Sparhawk Laboratories, Inc.

Gentamicin Piglet Injection (GENTAMICIN SULFATE, USP) Piglet Injection - 5 mg/mL

Piglet Injection Veterinary

Antibacterial

For Piglets Up to 3 days of age

For intramuscular use only.

ANADA#: 200-394 Approved by F.D.A

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, 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.

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.

Restricted Drug (California)--use only as directed.

Read accompanying directions carefully.

INDICATIONS

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

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 the vial with a suitable disinfectant, such as 70% alcohol. Use all precautions to prevent contamination of vial contents.

CONTRAINDICATIONS

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

PRECAUTIONS

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

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 the 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.

HOW SUPPLIED

Enter section text here

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

Protect from freezing.




For intramuscular use only.


TAKE TIME OBSERVE LABEL DIRECTIONS

Manufactured by
Sparhawk Laboratories, Inc.
Lenexa, KS 66215

G-6639-04

Rev. 2-09

<p>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 <i>E. coli</i> sensitive to gentamicin.</p> <p>G-6639-04 Rev. 2-09 LOT NO.: EXP. DATE:</p>	<p style="text-align: center;">Gentamicin Piglet Injection <hr/>(GENTAMICIN SULFATE, USP) <hr/>Piglet Injection Antibacterial 100 Doses 5mg/mL ANADA#: 200-394 Approved by F.D.A. NET CONTENTS: 3.4 oz (100 mL)</p> <p style="text-align: center;"> SPARHAWK LABORATORIES, INC.</p> <p style="text-align: center;"><small>DISTRIBUTED BY LENEXA, KS 66215 USA</small></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. Read accompanying directions carefully. Store between 2° and 30°C (36° and 86°F) Protect from freezing. For intramuscular use only.</p> <p>ANADA#: 200-394 Approved by F.D.A.</p> <p style="text-align: center;"><small>TAKE TIME  OBSERVE LABEL DIRECTIONS</small></p> <p style="text-align: center;"><small>Manufactured by Sparhawk Laboratories, Inc. Lenexa, KS 66215</small></p> <p style="text-align: right;"><small>OPEN HERE</small> </p>
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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 30°C (36° and 86°F)</p> <p>Protect from freezing.</p> <p>For intramuscular use only.</p> <p>ANADA#: 200-394 Approved by F.D.A.</p>  <p>Manufactured by Sparhawk Laboratories, Inc. Lenexa, KS 66215</p>	1	<p style="text-align: center;">Gentamicin Piglet Injection (GENTAMICIN SULFATE, USP)</p> <p style="text-align: center;">Piglet Injection- 5mg/mL</p> <p style="text-align: center;">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</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>	2
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3	<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>	4	<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>	5	<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. 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>	6
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GENTAMICIN PIGLET

gentamicin sulfate injection

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:58005-663
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GENTAMICIN SULFATE (UNII: 8X7386QRLV) (GENTAMICIN - UNII:T6Z9V48IKG)	GENTAMICIN	5 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58005-663-04	100 mL in 1 VIAL		
2	NDC:58005-663-05	250 mL in 1 VIAL		
3	NDC:58005-663-06	500 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200394	07/31/2007	

Labeler - Sparhawk Laboratories, Inc. (147979082)

Revised: 6/2013

Sparhawk Laboratories, Inc.