

GARASOL- gentamicin sulfate injection, solution
Merck Sharp & Dohme Corp.

Garasol®
(gentamicin injection)

Injection - 100 mg/mL
Anti-Infective for
Day-Old Chickens and
One- to Three-Day-Old
Turkeys

PRODUCT
INFORMATION

Approved by FDA under NADA # 101-862

CAUTION Federal law restricts this drug to use by or on the order of a licensed veterinarian

DESCRIPTION Each milliliter of GARASOL Injection contains 100 mg gentamicin base (equivalent to 156 mg gentamicin sulfate); 3.2 mg sodium bisulfite; 0.1 mg edetate disodium; 4.5 mg sodium acetate, anhydrous; 3.0 mg glacial acetic acid; 0.8 mg methylparaben and 0.1 mg propylparaben as preservatives; water for injection q.s.

CHEMISTRY Gentamicin is a bactericidal aminoglycoside antibiotic derived from *Micromonospora purpurea* of the Actinomycetes group. It is a powder, readily soluble in water and basic in nature. Gentamicin aqueous solutions do not require refrigeration and are stable over a wide range of temperatures and pH.

INDICATIONS Day-old chickens - GARASOL Injection is recommended for the prevention of early mortality associated with *Escherichia coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa* susceptible to gentamicin sulfate. Turkeys - As an aid in the prevention of early mortality of 1- to 3-day-old turkeys associated with *Arizona paracolon* infections susceptible to gentamicin sulfate.

DOSAGE AND ADMINISTRATION

Chickens: Each day-old chicken should be aseptically injected subcutaneously in the neck with GARASOL Injection diluted with sterile, physiologic saline solution to provide 0.2 mg gentamicin in a 0.2-mL dose. This concentration can be provided by diluting GARASOL Injection as follows:

GARASOL	Sterile		Dose/Chicken
mL	Saline	# Doses	mL
	mL		
1	99	500	0.2
2	198	1000	0.2
4	396	2000	0.2
10	990	5000	0.2

100 (1 bottle)	9900	50000	0.2
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Turkeys: Each 1- to 3-day-old turkey should be aseptically injected subcutaneously in the neck with GARASOL Injection diluted with sterile, physiologic saline solution to provide 1 mg gentamicin in a 0.2-mL dose. The dose should be injected under the loose skin on top of the neck, halfway between the head and base of the neck. This concentration can be provided by diluting GARASOL Injection as follows:

GARASOL mL	Sterile Saline mL	# Doses	Dose/Turkey mL
1	19	100	0.2
2	38	200	0.2
4	76	400	0.2
10	190	1000	0.2
100 (1 bottle)	1900	10000	0.2

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

Disinfect the injection site and top of the bottle with a suitable disinfectant, such as 70% isopropyl alcohol.

Use all precautions to prevent contamination of vial contents.

Residue Warnings For use in day-old chickens and 1- to 3-day-old turkeys only. Chickens injected with GARASOL Injection must not be slaughtered for food for at least 5 weeks following treatment. Turkeys injected with GARASOL Injection must not be slaughtered for food for at least 9 weeks following treatment.

HOW SUPPLIED GARASOL Injection, 100 mg/mL, is available in 100-mL multiple-dose vials, NDC 0061-0134-01.

Store between 2° and 30°C (36° and 86°F). Use within 28 days of first puncture and puncture a maximum of 10 times.

Intervet Inc. (d/b/a Merck Animal Health)
Madison, NJ 07940.

Formulated in Germany.

Rev. 03/2023

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MERCK

Animal Health

165573 R1

PRINCIPAL DISPLAY PANEL - 100 mL Vial Label

100 mg/mL

Sterile

Garasol®
(gentamicin injection)
Injection

Caution: Federal law restricts
this drug to use by or on the
order of a licensed veterinarian
(100 mL)

Approved by FDA under
NADA # 101-862

MERCK
Animal Health

Anti-infective for day-old chickens and 1- to 3-day-old turkeys.
Indications: Chickens: GARASOL Injection is recommended for the prevention of early mortality in day-old chickens associated with *Escherichia coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa* susceptible to gentamicin sulfate.
 Turkeys: As an aid in the prevention of early mortality of 1- to 3-day-old turkeys associated with *Arizona paracolon* infections susceptible to gentamicin sulfate.
Dose and Administration: Chickens: Inject each day-old chicken subcutaneously in the neck with GARASOL Injection diluted with sterile physiologic saline solution to provide 0.2 mg gentamicin in a 0.2-mL dose. Turkeys: Inject each 1- to 3-day-old turkey subcutaneously in the neck with GARASOL Injection diluted with sterile physiologic saline solution to provide 1 mg gentamicin in a 0.2-mL dose.
Residue Warnings: For use in day-old chickens only. Injected chickens must not be slaughtered for food for at least five (5) weeks following treatment. For use in 1- to 3-day-old turkeys only. Injected turkeys must not be slaughtered for food for at least nine (9) weeks following treatment. Store between 2° and 30°C (36° and 86°F). Use within 28 days of first puncture and puncture a maximum of 10 times.

100 mg/mL

Sterile

Garasol®

(gentamicin injection)
Injection

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian (100 mL)

Approved by FDA under
NADA # 101-862



Each mL contains: 100 mg gentamicin base (equivalent to 156 mg gentamicin sulfate); 3.2 mg sodium bisulfite; 0.1 mg edetate disodium; 4.5 mg sodium acetate, anhydrous; 3.0 mg glacial acetic acid; 0.8 mg methylparaben and 0.1 mg propylparaben as preservatives; water for injection q.s.
Read Product Information sheet carefully. FOR SUBCUTANEOUS USE ONLY.
 Gentamicin sulfate (active ingred.) Made in: See imprint. Formulated in Germany.
 Rev. 03/2023
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Restricted Drug (California) – use only as directed.

API Made In:
LOT:
EXP:

Varnish and Ink free

165093 R1

GARASOL

gentamicin sulfate injection, solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:0061-0134
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GENTAMICIN SULFATE (UNII: 8X7386QLV) (gentamicin - UNII:T6Z9V48IKG)	gentamicin	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0061-0134-01	100 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA101862	07/27/1983	

Labeler - Merck Sharp & Dohme Corp. (001317601)

Establishment

Name	Address	ID/FEI	Business Operations
Vet Pharma Friesoythe GmbH		341934053	MANUFACTURE

Revised: 11/2023

Merck Sharp & Dohme Corp.