SALIGARD 60- sodium salicylate solution Aurora Pharmaceutical, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

SaliGard™ Sodium Salicylate Concentrate 60% w/v

ACTIVE INGREDIENTS

Sodium Salicylate

60% w/v

OTHER INGREDIENTS

Water, sodium phosphate dibasic, hydrochloric acid

INDICATIONS

For use in the drinking water of poultry and swine as an aid in reducing pain, fever and inflammation.

DIRECTIONS FOR USE

For Analgesic and Antipyretic Use

Water Proportioner Use:

Add 6.5 ounces (192 mL) of Sodium Salicylate 60% Concentrate to make 1 gallon of stock solution and administer through a medicator metered at 1:128 (1 ounce per gallon). This will achieve a target dose of 11.3 mg/lb (25 mg/kg) body weight daily.

Livestock Tank Use:

Add 6.5 ounces (192 mL) of Sodium Salicylate 60% Concentrate to 128 gallons of drinking water. This will achieve a target dose of 11.3 mg/lb (25 mg/kg) body weight daily.

For Anti-Inflammatory/Anti-Prostaglandin Use — Day 1

Water Proportioner Use:

Add 14 ounces (414 mL) of Sodium Salicylate 60% Concentrate to make 1 gallon of stock solution and administer through a medicator metered at 1:128 (1 ounce per gallon). This will achieve a target dose of 22.7 mg/lb (50 mg/kg) body weight daily.

Livestock Tank Use:

Add 14 ounces (414 mL) of Sodium Salicylate 60% Concentrate to 128 gallons of drinking water. This will achieve a target dose of 22.7 mg/lb (50 mg/kg) body weight daily.

Day 2 through 7

Water Proportioner Use:

Add 8 ounces (236 mL) of Sodium Salicylate 60% Concentrate to make 1 gallon of stock solution and administer through a medicator metered at 1:128 (1 ounce per gallon). This will achieve a target dose of 13.6 mg/lb (30 mg/kg) body weight daily.

Livestock Tank Use:

Add 8 ounces (236 mL) of Sodium Salicylate 60% Concentrate to 128 gallons of drinking water. This will achieve a target dose of 13.6 mg/lb (30 mg/kg) body weight daily.

Prepare fresh solutions daily. Repeat as necessary.

WARNING

Do not administer concentrated solution by direct oral administration — gastro-intestinal irritation or overdose may occur.

Do not use in piglets less than 3 weeks of age.

Do not use if allergic or sensitive to the active ingredients.

STORAGE

Store at 20°-25° C (68°-77° F). Excursions permitted between 15°-30° C (59°-86° F).

CAUTION

Keep container closed when not in use. Product may solidify at cold storage temperatures. Place container in room temperature storage, which will thaw the solution. If precipitate remains after thawing, place in warm water. Gently invert container to ensure dissolution and uniformity of product. Gradual darkening will not affect product stability.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.



MANUFACTURED IN THE USA

REORDER NO: 21002

MANUFACTURED BY:

Aurora Pharmaceutical, Inc.

NORTHFIELD, MINNESOTA 55057 1-888-215-1256 www.aurorapharmaceutical.com IN 50-1714 09/2021

PRINCIPAL DISPLAY PANEL - 3.79 Liter Bottle Label

NDC 51072-117-00

SaliGardTM

Sodium Salicylate Concentrate 60% w/v

For Use in Livestock Only

Keep Out of Reach of Children

Net Contents:

1 Gallon (3.79 Liters)

AURORA PHARMACEUTICAL®



SALIGARD 60

Product Information Product Type OTC ANIMAL DRUG Item Code (Source) NDC:51072-117 Route of Administration ORAL Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM SALICYLATE (UNII: WQ1H85SYP) (SALICYLIC ACID - UNII: O414PZ 4LPZ)	SODIUM SALICYLATE	60 g in 100 mL

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:51072-117-00	3790 mL in 1 BOTTLE				

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
	05/04/2022			
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date		

Labeler - Aurora Pharmaceutical, Inc. (832848639)

Establishment						
Name	Address	ID/FEI	Business Operations			
Aurora Pharmaceutical, Inc.		832848639	manufacture			

Revised: 5/2022 Aurora Pharmaceutical, Inc.