SODIUM SALICYLATE CONCENTRATE- sodium salicylate solution
Aurora Pharmaceutical LLC

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.

ORAL-PRO™
Sodium Salicylate
Concentrate 48.6% w/v

ACTIVE INGREDIENT	
Sodium Salicylate	48.6% w/v

CALF LABEL CLAIM

Indications For Use, Calves

Supportive treatment of pyrexia in acute respiratory disease, in combination with appropriate (e.g., anti-infective) therapy if necessary.

Contraindications, Calves

Do not use Sodium Salicylate in neonates or calves less than 2 weeks of age.

Dosage, Calves

40 mg Sodium Salicylate per kg body weight (4 mL per 100 lbs.) once daily, for 1–3 days. Administer orally in drinking water or milk (replacer).

Recommended withdrawal period for all food animals following use at "usual dosages": meat 24 hours.

SWINE AND POULTRY LABEL CLAIM

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 8 ounces (236 mL) of Sodium Salicylate 48.6% 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 8 ounces (236 mL) of Sodium Salicylate 48.6% 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

Water Proportioner Use:

Add 16 ounces (473 mL) of Sodium Salicylate 48.6% 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 16 ounces (473 mL) of Sodium Salicylate 48.6% Concentrate to 128 gallons of drinking water. This will achieve a target dose of 22.7 mg/lb (50 mg/kg) body weight daily.

Following Days

Water Proportioner Use:

Add 10 ounces (296 mL) of Sodium Salicylate 48.6% 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 10 ounces (296 mL) of Sodium Salicylate 48.6% 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 4 weeks of age.

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

Do not use in food-producing animals less than 1 day prior to slaughter.

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, or place in warm water. Gently invert container to ensure uniformity of product.

Gradual darkening will not affect product stability.

MANUFACTURED IN THE USA

REORDER NO: 21004

MANUFACTURED BY:
Aurora Pharmaceutical, LLC
NORTHFIELD, MINNESOTA 55057
888-215-1256
www.aurorapharmaceutical.com
IN 50-1108 REV 03

PRINCIPAL DISPLAY PANEL - 3.79 Liters Bottle Label

NDC 51072-038-01

ORAL-PRO™

Sodium Salicylate

Concentrate 48.6% w/v

For Use in Livestock Only

Keep Out of Reach of Children

Net Contents:
1 Gallon (3.79 Liters)

aurora
PHARMACEUTICAL®

ACTIVE INGREDIENT
Sodium Salicylate. . . . . 48.6% w/v

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TAKE TIME OBSERVE LABEL DIRECTIONS

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Sodium Salicylate
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For Use in Livestock Only

Keep Out of Reach of Children

Net Contents:
1 Gallon (3.79 Liters)

aurora PHARMACEUTICAL

DIRECTIONS FOR USE (continued)
For Anti-Inflammatory/Anti-Prostaglandin Use
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SODIUM SALICYLATE CONCENTRATE

sodium salicylate solution

Product Information

Product Type	OTC ANIMAL DRUG LABEL	**Item Code (Source)**	NDC:51072-038
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM SALICYLATE (SALICYLIC ACID)	SODIUM SALICYLATE	48.6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water	69.8 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51072-038-01	3790 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/16/2011	

Labeler - Aurora Pharmaceutical LLC (832848639)

Establishment

Name	Address	ID/FEI	Business Operations
Aurora Pharmaceutical LLC		832848639	MANUFACTURE

Revised: 8/2013 Aurora Pharmaceutical LLC