

SODIUM SALICYLATE- 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.

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).

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 - Day 1

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.

Day 2 through 7

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 3 weeks of age.

Storage

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

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

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.

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: 21004

MANUFACTURED BY:

Aurora Pharmaceutical, Inc.

NORTHFIELD, MINNESOTA 55057

1-888-215-1256

www.aurorapharmaceutical.com

IN 50-1108 02/2021

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®

The image shows a detailed view of the product label for ORAL-PRO Sodium Salicylate Concentrate 48.6% w/v. The label is yellow with a blue and red curved graphic at the top. The product name 'ORAL-PRO' is prominently displayed in a red box. Below it, 'Sodium Salicylate Concentrate 48.6% w/v' is written in large black font. The label includes sections for 'ACTIVE INGREDIENT', 'Calf Label Claim', 'Swine and Poultry Label Claim', 'Directions for Use' (with sub-sections for Analgesic/Antipyretic and Anti-inflammatory use), 'Warnings', 'Storage', and 'Caution'. A barcode is located at the bottom left, and the Aurora Pharmaceutical logo is at the bottom right. A warning box at the very bottom right states: 'Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.'

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 (replace).

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. (continued on next panel)

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TAKE TIME
 OBSERVE LABEL DIRECTIONS

MANUFACTURED IN THE USA

ORAL-PRO®

**Sodium Salicylate
Concentrate 48.6% w/v**

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Net Contents:
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aurora
PHARMACEUTICAL

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SODIUM SALICYLATE

sodium salicylate solution

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM SALICYLATE (UNII: MQ1H85SYP) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SODIUM SALICYLATE	48.6 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, Inc. (832848639)

Establishment

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

Revised: 12/2021

Aurora Pharmaceutical, Inc.