ORAL-PRO SODIUM SALICYLATE WITH CAFFEINE- 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 60% w/v
with Caffeine 5.7% w/v

ACTIVE INGREDIENTS	
Sodium Salicylate	60% w/v
Caffeine	5.7% w/v

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 with Caffeine 5.7% 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 with Caffeine 5.7% 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 with Caffeine 5.7% 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 with Caffeine 5.7% 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 with Caffeine 5.7% 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 with Caffeine 5.7% 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.

Store 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.

In California, Restricted Drug - Use Only as Directed

MANUFACTURED IN THE USA

REORDER NO: 21003

MANUFACTURED BY:
Aurora Pharmaceutical, LLC
NORTHFIELD, MINNESOTA 55057
888-215-1256
www.aurorapharmaceutical.com
IN 50-1110 12/2017

PRINCIPAL DISPLAY PANEL - 3.79 Liter Bottle Label

NDC 51072-039-01

ORAL-PRO®

Sodium Salicylate
Concentrate 60% w/v
with Caffeine 5.7% w/v

For Use in Livestock Only

Keep Out of Reach of Children

Net Contents:
1 Gallon (3.79 Liters)

AURORA PHARMACEUTICAL®

ORAL-PRO SODIUM SALICYLATE WITH CAFFEINE

sodium salicylate solution

Product Information

Product Type	OTC ANIMAL DRUG	**Item Code (Source)**	NDC:51072-039
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM SALICYLATE (UNII: WIQ1H85SYP) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SODIUM SALICYLATE	60 g in 100 mL
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	5.7 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51072-039-01	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