REVASOL CHILDRENS ALLERGY- diphenhydramine hcl liquid Rnv LLC

REVASOL CHILDRENS ALLERGY

Active ingredient (in each 5 mL) Purpose

Diphenhydramine HCl 12.5mg......Antihistamine

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose sneezing itchy, watery eyes itching of the nose or throat

Warnings

Do not use • to make a child sleepy • with any other product containing diphenhydramine, even on one used on skin

Ask a doctor before use if the child has

• a breathing problem such as chronic bronchitis • glaucoma

Ask a doctor or pharmacist before use if the child is taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- find the right dose on chart below
- mL=mililiter take every 4 to 6 hours, or as directed by a doctor do not take more than 6 doses in 24 hours use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

Age	Dose
children 6 to 11 years	5 mL to 10 mL
children 2 to 5 years	do not use unless directed by a doctor
children under 2 years	do not use

Other information

- each 5 mL contains: sodium 4 mg
- store between 15-30°C (59-86°F).
- TAMPER-EVIDENT FEATURE: Do not use if printed safety seal is torn, broken or

missing.

Inactive ingredients

anhydrous citric acid, D&C Red #33, FD&C Red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose.

Questions or comments 1-888-446-4753

Monday - Friday (9 AM - 5 PM EST)



Drug Facts	
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▶

Compare to the active ingredient in Children's Benadryl® Allergy Liquid*

Drug Facts (continued)

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Questions or comments 1-888-446-4753

Monday - Friday (9 AM - 5 PM EST)

Made in USA Distributed by:

14501 NW 60 Ave Miami Lakes, FL 33014

*This product is not manufactured or distributed by Johnson and Johnson Corporation, owner of the registered trademark ChidIren's Benadryl® Allergy.

Lot:

REVASOL CHILDRENS ALLERGY

diphenhydramine hcl liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:84379-286

Route of Administration ORAL

Active Ingredient/Active Moiety

Basis of Ingredient Name Strength Strength DIPHENHYDRAMINE HCL (UNII: TC2D6JAD40) (DIPHENHYDRAMINE -**DIPHENHYDRAMINE** 12.5 mg UNII:8GTS82S83M) HCL in 5 mL

Inactive Ingredients

Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
SORBITOL SOLUTION 70% (UNII: 8KW3E207O2)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

SODIUM CITRATE (UNII: 1Q73Q2JULR)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
MENTHOL (UNII: L7T10EIP3A)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics		
Color		Score
Shape		Size
Flavor	CHERRY	Imprint Code
Contains		

Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:84379-286- 04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/12/2025	

Labeler - Rnv LLC (118917568)

Registrant - Rnv LLC (118917568)

Establishment			
Name	Address	ID/FEI	Business Operations
Rnv LLC		118917568	manufacture(84379-286)

Revised: 3/2025 Rnv LLC