ALLERGY RELIEF- diphenhydramine hcl liquid KRAMER NOVIS

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Allergy Relief

Drug Facts

Active Ingredient (in each 5 mL tsp)

Diphenhydramine HCL, 12.5 mg

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

Temporarily relieves these symptoms due to the common cold:

• runny nose • sneezing

Warnings

Do not use

- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to the enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product:

- excitability might occur, especially in children
- marked drowsiness may occur avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness effect
- be careful when driving a motor vehicle or operating machinery

If pregnant or breast-feeding, ask a health professional before use.

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

Directions

- Take every 4 to 6 hours, or as directed by doctor.
- Do not exceed recommended dose.

Adults and Children 12 years of age and	take 10 to 20 mL (2 to 4 tsp) not to exceed 300 mg in 24		
over:	hours		
Children 6 to under 12 years of age:	take 5 to 10 mL (1 to 2 tsp) not to exceed 150 mg in 24 hours		
Children under 6 years of age:	consult a doctor		

Other information

- Store at controlled room temperature 15°-30°C (59°-86°F).
- Do not refrigerate. Avoid excessive heat or humidity.
- Protect from light.

Inactive ingredients

Cherry flavor, citric acid, FD&C Red #40, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sorbitol, and sucralose

Questions or comments?

Call weekdays from 8 AM to 4 PM AST at 1-787-767-2072 | www.kramernovis.com

Manufactured in the USA for Kramer Novis, San Juan, PR 00917

Compare to the active ingredient of Benadryl[®] Allergy Liquid*

Relieves:

- $\sqrt{\mathbf{Runny Nose}}$
- \checkmark Sneezing
- $\sqrt{1}$ Itchy, Watery Eyes
- √ Itchy Throat
- Cherry Flavor

Alcohol Free

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Benadryl[®] Allergy.

TAMPER EVIDENT: DO NOT USE IF SEAL UNDER CAP IS TORN, BROKEN OR MISSING.

Packaging

Drug Facts	NDC 52083-665-16	Drug Facts (continued)	
Active Ingredient (in each 5 mL tsp) Purpose Diphenhydramine HCl, 12.5 mg. Antihistamine Uses Funporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itching of the nose or throat Temporarily relieves these symptoms due to the common cold: • runny nose • sneezing • itching of the nose • sneezing	Allergy Relief	Directions Take every 4 to 6 hours, or as directed by doctor Do not exceed recommended dose. Adults and Children 12 years of age take 10 to 20 mL (2 to 4 tsp) not to exceed 300 mg in 24 hours Children 6 to under 12 years of age: take 5 to 10 mL (1 to 2 tsp) not to exceed 150 mg in 24 hours Children under 6 years of age: consult a doctor	
Warnings Do not use with any other product containing diphenhydramine, even one used on skin to make a child sleepy Ask a doctor before use if you have a breathing problem such as emphysema or chronic bronchitis	Antihistamine Diphenhydramine HCl, 12.5 mg/5 mL Compare to the active ingredient of Benadryl [®] Allergy Liquid [®] Relieves:	Other information Store at controlled room temperature 15° - 30°C (59° - 86°F). Do not refrigerate. Avoid excessive heat or humidity. Protect from light. Protect from light. Cherry flavor, citric acid, FD&C Red #40, glycerin, methylparaben, propylene	
Bolcoma glaucoma trouble urinating broach as chiph joint and union broaching trouble urinating due to the enlarged prostate gland Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers When using this product: excitability might occur, especially in children	 ✓ Runny Nose ✓ Sneezing ✓ Itchy, Watery Eyes ✓ Itchy Throat ✓ Alcohol Free 	glycol, propylparaben, purified water, sodium citrate, sorbitol, and sucralose Questions or comments? Call weekdays from 8 AM to 4 PM AST at 1-787-767-2072 www.kramernovis.com Manufactured in the USA for Kramer Novis San Juan, PR 00917 *This product is not manufactured or distributed by McNeil Consumer	
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ALLERGY RELIEF

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Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-665		
Route of Administration	ORAL				

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL

Inactive Ingredients				
	Ingredient Name		Strength	
CITRIC ACID MONOHYDRATE (UN	III: 2968PHW8QP)			
FD&C RED NO. 40 (UNII: WZB91272	KOA)			
GLYCERIN (UNII: PDC6A3C0OX)				
METHYLPARABEN (UNII: A2I8C7HI	θT)			
PROPYLENE GLYCOL (UNII: 6 DC9	Q167V3)			
PROPYLPARABEN (UNII: Z8IX2SC1	OH)			
WATER (UNII: 059QF0KO0R)				
SODIUM CITRATE, UNSPECIFIED	F ORM (UNII: 1Q73Q2JULR)			
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color		Score		

Shape			Size		
Flavor	CHERRY Imprint Code				
Contains					
Packaging					
# Item Code	Package Description		Marketing Start Date	Marketing End Date	
1 NDC:52083-665-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product		03/02/2020		
Marketing Information					
Marketing Category	Applica	tion Number or Monograph	Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341			03/02/2020	

Labeler - KRAMER NO VIS (090158395)

Revised: 3/2020

KRAMER NOVIS