DIPHENHYDRAMINE ORAL LIQUID- diphenhydramine hydrochloride liquid
Rij Pharmaceutical Corporation

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.

Drug Facts

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Active ingredient in each 5 mL (in one teaspoonful)

Diphenhydramine HCl, USP 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 common cold:

- runny nose
- sneezing

Warnings

Do not use

- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis.
- a sodium-restricted diet

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

When using this product

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

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 right away.

Directions

- take every 4-6 hours
- Do not use more than 6 times in 24 hours

adults and children 12 years of age and over	2 to 4 teaspoonfuls (25 to 50 mg)
children 6 to under 12 years of age	1 to 2 teaspoonfuls (12.5 to 25 mg)
children under 6 years	ask a doctor

Other information

- store at room temperature 15º - 30°C (59º - 86°F)
- protect from freezing.
- protect from light.
- each teaspoon (5 mL) contains: sodium 16 mg
- **TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING**

Inactive ingredients

citric acid, D & C Red #33, FD & C Red #40, flavor, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, sucrose, water.

PRINCIPAL DISPLAY PANEL

DIPHENHYDRAMINE ORAL LIQUID

diphenhydramine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53807-204
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine -	Diphenhydramine	12.5 mg

UNII:8GTS82S83M)	Hydrochloride	in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Anhydrous Citric Acid (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
Sodium Benzoate (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
Water (UNII: 059QF0KO0R)	

Product Characteristics			
Color	PINK	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53807-204-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
2	NDC:53807-204-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
3	NDC:53807-204-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/16/1999	

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679156	manufacture(53807-204)

Revised: 4/2018 Rij Pharmaceutical Corporation