

DIPHENHIST- diphenhydramine hydrochloride liquid

Rebel Distributors Corp

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.

Diphenhist

Drug Facts

Active ingredient (in each 5mL teaspoonful)

Diphenhydramine HCl USP 12.5 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms of hay fever or other upper respiratory allergies

- runny nose
- sneezing
- itchy, water eyes
- itchy nose or throat

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

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

When using this product

- you may get very drowsy
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- 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 take more than 6 doses in 24 hours
-

adults and children 12 years and over	2 - 4 teaspoonfuls
children 6 to under 12 years	1 - 2 teaspoonfuls
children under 6	do not use

Other information

- **each teaspoonful (5 mL) contains:**
sodium 5 mg
- store between 20°-25° C (68°-77°F)
- protect from light. Store in outer carton until contents used

Inactive ingredients

artificial cherry flavor, citric acid, D&C red #33, FD&C red #40, glycerin, polysorbate 20, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol solution

Questions or comments?

call **1-800-645-2158**, 9 am - 5pm ET, Monday - Friday

PRINCIPAL DISPLAY PANEL

COMPARE TO
ACTIVE INGREDIENT IN
BENADRYL[®]
ALLERGY LIQUID*

CHILDREN'S ALCOHOL-FREE
ALLERGY MEDICATION

Diphenhist[®]

ORAL SOLUTION

Diphenhydramine HCl, USP

Antihistamine

For Temporary Relief of

Symptoms of Upper

Respiratory Allergies

and Hay Fever

4 fl oz

(118 mL)

Peel

4oz Oral Solution Rx# Master
Lot #: 000000 Exp. Date: 00/00/00
NDC 42254-184-04 AWP: \$7.56

Peel

4oz Oral Solution Rx# Master
Lot #: 000000 Exp. Date: 00/00/00
NDC 42254-184-04 AWP: \$7.56



NDC 42254-184-04

Diphenhist (Diphenhydramine) 12.5mg/5ml

4oz Oral Solution

Each 5ml(tsp) contains: Diphenhydramine HCl, USP 12.5mg Antihistamine

See box Alcohol-Free and Cherry Flavor.

Product ID: SD018404

Mfr. By: Rugby Laboratories, Inc. Duluth, Georgia 30097

Peel

4oz Oral Solution Rx# Master
Lot #: 000000 Exp. Date: 00/00/00
NDC 42254-184-04 AWP: \$7.56

Peel

4oz Oral Solution Rx# Master
Lot #: 000000 Exp. Date: 00/00/00
NDC 42254-184-04 AWP: \$7.56



SD018404

Distributed by: Physician Partner, Thousand Oaks, CA 91320 www.physicianpartner.com
 Store at controlled room temperature 15°-30° C (59°-86°F) Keep medication out of the reach of children.

DIPHENHIST

diphenhydramine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42254-184(NDC:0536-0770)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	12.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
Glycerin (UNII: PDC6A3C0OX)	
Polysorbate 20 (UNII: 7T1F30V5YH)	

Water (UNII: 059QF0KO0R)				
Sodium Benzoate (UNII: OJ245FE5EU)				
Sodium Citrate (UNII: 1Q73Q2JULR)				
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)				
Sorbitol (UNII: 506T60A25R)				
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:42254-184-04	118 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	09/26/2009		

Labeler - Rebel Distributors Corp (118802834)

Establishment			
Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK