

ALLERGY RELIEF CHILDRENS- diphenhydramine hcl solution
Major Pharmaceuticals

Major 44-015

Active ingredient (in each 5 mL)

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

Warnings

Do not use

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

Ask a doctor before use if the child has

- glaucoma
- a breathing problem such as chronic bronchitis

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 reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **do not take more than directed**
- do not take more than 6 doses in 24 hours
- mL = milliliter
- only use the dose cup provided
- find right dose on chart below
- take every 4 to 6 hours, or as directed by a doctor

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

Other information

- **each 5 mL contains:** sodium 4 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number
- protect from light

Inactive ingredients

anhydrous citric acid, D&C red #33, FD&C red #40, flavor, glycerin, high fructose corn syrup, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sucrose

Questions or comments?

1-800-426-9391

Principal display panel

MAJOR®

NDC 0904-7533-15

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

children's
allergy relief

diphenhydramine HCl,
12.5 mg per 5 mL
oral solution

antihistamine

relieves:

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

ages 6 to

11 years

cherry flavored

alcohol free

16 FL OZ

(473 mL)

TAMPER EVIDENT: DO NOT USE IF PRINTED
NECK WRAP IS BROKEN OR MISSING

*This product is not manufactured or distributed by Kenvue Inc.,
owner of the registered trademark Children's Benadryl® Allergy.
50844 REV0724A01521

Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

www.major-rugby.com

MAJOR® NDC 0904-7533-15
compare to the active ingredient in
Children's Benadryl® Allergy*

children's allergy relief

**diphenhydramine HCl,
12.5 mg per 5 mL oral solution**

antihistamine

relieves:

- sneezing • runny nose
- itchy, watery eyes
- itchy throat or nose

ages 6 to 11 years

16 FL OZ (473 mL) alcohol free

cherry flavored



Drug Facts

**TAMPER EVIDENT: DO NOT USE IF
PRINTED WRAP IS BROKEN OR MISSING**

Active ingredient (in each 5 mL)	Purpose
Diphenhydramine HCl 12.5 mg	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 one used on skin

Ask a doctor before use if the child has

- glaucoma ■ a breathing problem such as chronic bronchitis

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 reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions ■ do not take more than directed

- do not take more than 6 doses in 24 hours
- mL = milliliter
- only use the dose cup provided
- find right dose on chart below
- take every 4 to 6 hours, or as directed by a doctor

Drug Facts (continued)

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

Other information ■ each 5 mL contains: sodium 4 mg

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package
- protect from light

Inactive ingredients

anhydrous citric acid, D&C red #33, FD&C red #40, flavor, glycerin, high fructose corn syrup, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sucrose

Questions or comments? 1-800-426-9391

*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Children's Benadryl® Allergy.
50844 REV0724A01521 Rev. 07/25 M-17 Re-order No. 701422

Distributed by:
MAJOR® PHARMACEUTICALS
Indianapolis, IN 46268
(800) 616-2471
www.major-rugby.com



3 09047 53315 2

No Print / No Varnish Area
Lot # and Exp. Info

Major 44-015

ALLERGY RELIEF CHILDRENS

diphenhydramine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7533
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7533-20	1 in 1 CARTON	03/07/2025	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0904-7533-15	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/07/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/07/2025	

Labeler - Major Pharmaceuticals (191427277)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(0904-7533) , pack(0904-7533)

Revised: 3/2026

Major Pharmaceuticals