CHILDRENS BENADRYL DYE-FREE ALLERGY- diphenhydramine hydrochloride solution
Johnson & Johnson Consumer Inc.

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.

Children's Benadryl ® DYE-FREE ALLERGY

Drug Facts

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

- 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 reach of children. In case of overdose, get medical help or contact a

Poison Control Center right away. (1-800-222-1222)

Directions

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

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

Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

Other information

- **each 5 mL contains:** sodium 10 mg
- store between 20-25°C (68-77°F)
- **do not use if carton tape or bottle wrap imprinted with "Sealed For Your Safety" is broken or missing**
- see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, flavors, glycerin, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol solution

Questions or comments?

call **1-877-717-2824** or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

NDC 50580-535-01

Children's
Benadryl ®

DYE-FREE ALLERGY

Diphenhydramine HCl/antihistamine
12.5 mg/5 mL oral solution

4-6 Hours/Dose

RELIEF OF:

- Runny Nose
- Sneezing
- Itchy,Watery Eyes
- Itchy Throat or Nose

✔ Free Of:
- Dyes
- Alcohol
- Sugar
- Parabens
- High Fructose Corn Syrup

Bubble Gum!
Flavored Liquid

4 fl oz (118 mL)

Children's Benadryl®

How can we help?

1-877-717-2824

benadryl.com

NDC 50580-535-01

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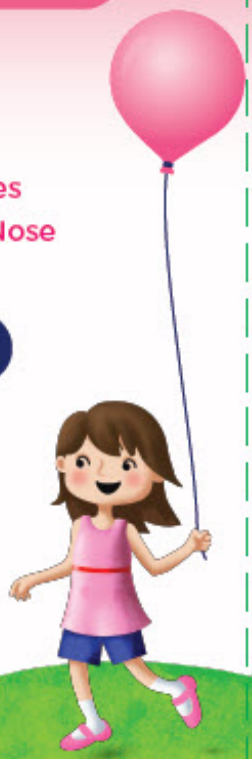


Bubble Gum!
Flavored Liquid

Children's Benadryl®

DYE-FREE ALLERGY

Tips for Outdoor Allergens:

- Avoid being outside when the pollen count is high, typically in the morning
- Shower and change clothing after spending time outdoors

Tips for Indoor Allergens:

- Wash sheets and blankets in hot water and use the dryer weekly
- Minimize contact and keep pets out of the bedroom to help with pet allergies

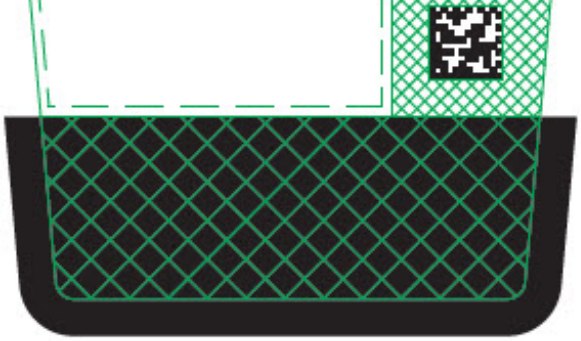
For more information, visit:

www.benadryl.com

4 fl oz (118 mL)

Active ingredient made in Japan
Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA

30048562



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Drug Facts (continued)

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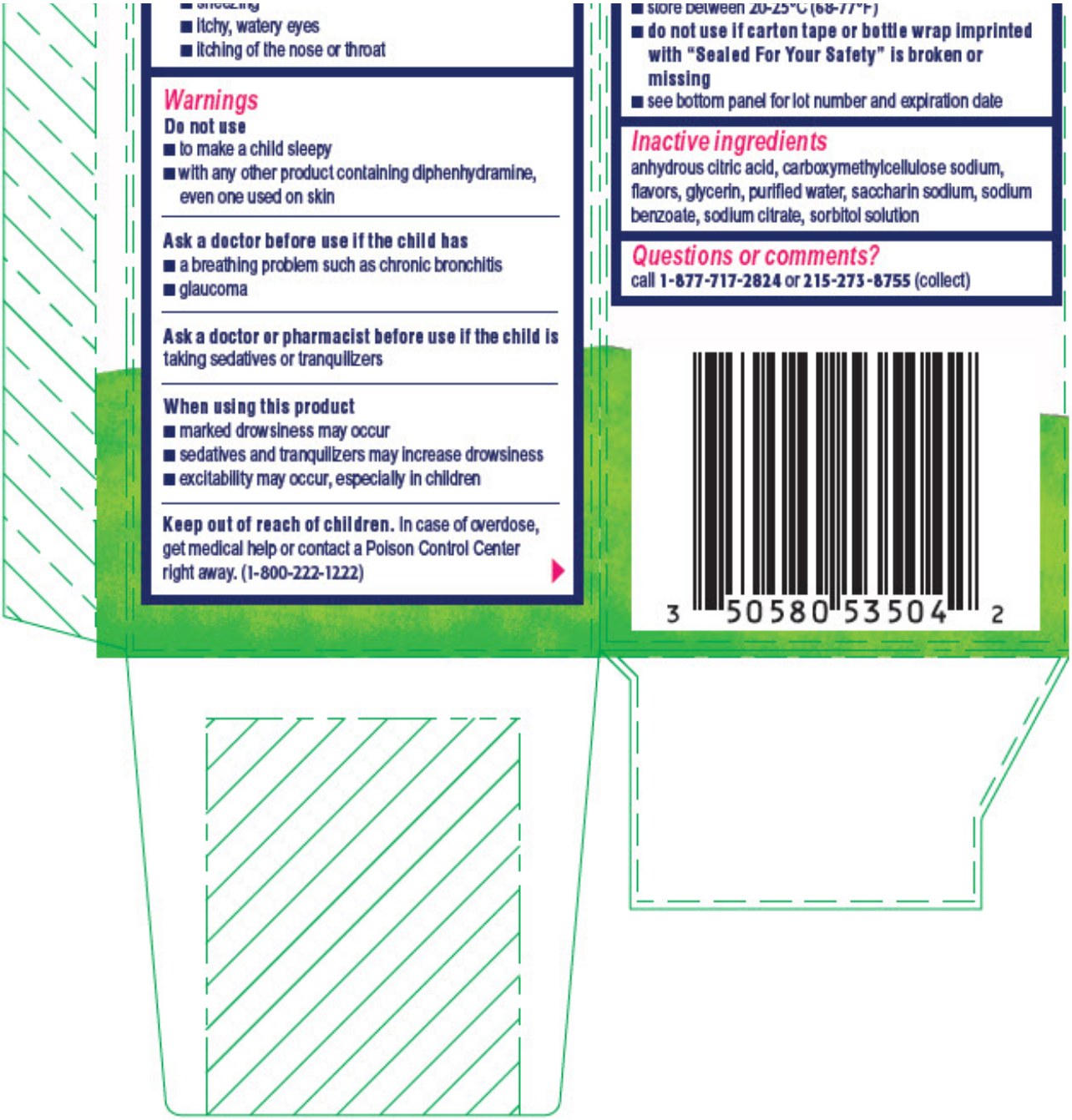

CHILDRENS BENADRYL DYE-FREE ALLERGY

diphenhydramine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-535
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)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

Color	white (Clear, colorless)	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-535-01	1 in 1 CARTON	12/01/2015	
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:50580-535-08	1 in 1 CARTON	06/16/2022	
2		236 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2008	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 3/2023 Johnson & Johnson Consumer Inc.