

**CHILDRENS BENADRYL ALLERGY- diphenhydramine hydrochloride solution**  
**Kenvue Brands LLC**

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**Children's Benadryl® 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
- a sodium-restricted diet

**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 14 mg
- store between 20-25°C (68-77°F). Protect from light. Store in outer carton until contents used.
- **do not use if bottle wrap or foil inner seal imprinted with “Sealed For Your Safety” is broken or missing**

## Inactive ingredients

anhydrous citric acid, D&C red no. 33, FD&C red no. 40, flavors, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucrose

## Questions or comments?

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

## PRINCIPAL DISPLAY PANEL

NDC 50580-534-04

Children's

Benadryl<sup>®</sup>

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

Alcohol Free

Cherry!

Flavored

4 fl oz (118 mL)

Children's  
**Benadryl**<sup>®</sup>

**ALLERGY**  
ALERGIA

*How can we help?*

*¿Cómo podemos ayudarlo?*

**1-877-717-2824**  
**benadryl.com**

NDC 50580-534-04

Children's  
**Benadryl**<sup>®</sup>

**ALLERGY**  
ALERGIA

**Diphenhydramine HCl/antihistamine**  
**12.5 mg/5 mL oral solution**

**Difenhidramina ClH/antihistamínico**  
**12.5 mg/5 ml solución oral**

**4-6** Hours/Dose  
Horas/Dosis

**RELIEF OF:**  
ALIVIA:

 **Runny Nose**  
Secreción nasal

**Drug Facts**

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|-------------------------------------|---------------|
| Diphenhydramine HCl 12.5 mg.....    | Antihistamine |

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✓ **Sneezing**  
Estornudos

✓ **Itchy, Watery Eyes**  
Lagrimo, picazón en los ojos

✓ **Itchy Throat or Nose**  
Picazón de garganta o nariz



Alcohol Free  
Sin alcohol



**Cherry!** **iCereza!**  
Flavored Saborizado

4 fl oz (118 mL)



LOT/EXP

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Children's  
**Benadryl**

ALLERGY  
ALERGIA

Etiqueta de información

### Etiqueta de información (continuación)

#### Posología

- encuentre la dosis adecuada en el siguiente cuadro
- ml = mililitro
- tomar cada 4 a 6 horas, o según lo indicado por el médico
- no tomar más de 6 dosis en 24 horas

| Edad (años)             | Dosis (ml)                           |
|-------------------------|--------------------------------------|
| niños menores de 2 años | no usar                              |
| niños de 2 a 5 años     | no usar, salvo por indicación médica |
| niños de 6 a 11 años    | 5 ml a 10 ml                         |

## Etiqueta de información

### **Ingrediente activo Acción terapéutica (cada 5 ml)**

Difenhidramina ClH 12.5 mg.....Antihistamínico

### **Indicaciones**

- alivia temporalmente estos síntomas por rinitis alérgica u otras alergias del tracto respiratorio superior:
  - secreción nasal
  - estornudos
  - lagrimeo, picazón en los ojos
  - comezón en la nariz o la garganta

### **Advertencias**

#### **No usar**

- para dormir a un niño
- con otro producto que contenga difenhidramina, incluso si es de uso tópico

#### **Consulte a su médico antes de usar si el niño**

- tiene problemas respiratorios, como bronquitis crónica
- tiene glaucoma
- sigue una dieta baja en sodio

#### **Consulte a un médico o farmacéutico antes de usar este producto si el niño toma sedantes o tranquilizantes**

#### **Al usar este producto**

- puede sentir una marcada somnolencia
- los sedantes y tranquilizantes pueden aumentar la somnolencia
- puede causar excitabilidad, especialmente en niños

**Mantener fuera del alcance de los niños.** En caso de sobredosis, busque ayuda médica o comuníquese con un centro de toxicología de inmediato. (1-800-222-1222) ▶

niños de 6 a 11 años 1.5 ml a 10 ml

**Atención:** usar solo el dosificador que se incluye, diseñado exclusivamente para usar con este producto. No usar ningún otro dispositivo de dosificación.

### **Otra información**

- **cada 5 ml contiene:** sodio 14 mg
- almacenar a 20-25 °C (68-77 °F). Proteger de la luz. Almacenar en el envase exterior hasta haber utilizado su contenido.
- **no usar si se ha roto o falta el envoltorio de la botella o el sello interior de papel aluminio impreso con las palabras "Sealed For Your Safety"**

### **Ingredientes inactivos**

ácido cítrico anhidro, rojo n.° 33 D&C, rojo n.° 40 FD&C, saborizantes, glicerina, glicirricinato de monoamonio, poloxámero 407, agua purificada, benzoato de sodio, cloruro de sodio, citrato de sodio, sacarosa

### **¿Tiene preguntas o comentarios?**

llame al **1-877-717-2824** o al **215-273-8755** (cobro revertido)

Active ingredient made in Japan /  
Ingrediente activo hecho en Japón

Distributed by / Distribuido por:  
**JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
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Pat. www.jjciipats.com 30053652

**For more information:**  
Para obtener más información:

**www.benadryl.com**

## CHILDRENS BENADRYL ALLERGY

diphenhydramine hydrochloride solution

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:50580-534 |
| <b>Route of Administration</b> | ORAL           |                           |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>   | <b>Basis of Strength</b>         | <b>Strength</b>    |
|--|----------------------------------|--------------------|
| <b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40)<br>(DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE<br>HYDROCHLORIDE | 12.5 mg<br>in 5 mL |

**Inactive Ingredients**

| <b>Ingredient Name</b>                                     | <b>Strength</b> |
|--|-----------------|
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)            |                 |
| <b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)               |                 |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)              |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                         |                 |
| <b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)           |                 |
| <b>POLOXAMER 407</b> (UNII: TUF21VW3M2)                    |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                            |                 |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)                  |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)                  |                 |
| <b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR) |                 |
| <b>SUCROSE</b> (UNII: C151H8M554)                          |                 |

**Product Characteristics**

|                 |        |                     |  |
|-----------------|--------|---------------------|--|
| <b>Color</b>    | red    | <b>Score</b>        |  |
| <b>Shape</b>    |        | <b>Size</b>         |  |
| <b>Flavor</b>   | CHERRY | <b>Imprint Code</b> |  |
| <b>Contains</b> |        |                     |  |

**Packaging**

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                                | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---|-----------------------------|---------------------------|
| 1        | NDC:50580-534-04 | 1 in 1 CARTON   | 07/01/2008                  |                           |
| 1        |                  | 118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package |                             |                           |
| 2        | NDC:50580-534-08 | 1 in 1 CARTON   | 07/01/2008                  |                           |
| 2        |                  | 236 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package |                             |                           |
| 3        | NDC:50580-534-16 | 2 in 1 PACKAGE  | 01/28/2009                  | 12/28/2022                |
| 3        |                  | 1 in 1 CARTON   |                             |                           |
| 3        |                  | 236 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package |                             |                           |
| 4        | NDC:50580-534-18 | 2 in 1 PACKAGE  | 04/12/2021                  |                           |
| 4        |                  | 1 in 1 CARTON   |                             |                           |
| 4        |                  | 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 Drug | M012                                     | 07/01/2008           |                    |

**Labeler** - Kenvue Brands LLC (118772437)

Revised: 11/2024

Kenvue Brands LLC