

**CHILDRENS BENADRYL ALLERGY- diphenhydramine hydrochloride solution**  
**Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division**

*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.*

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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

<b>Age (yr)</b>	<b>Dose (mL)</b>
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 carton tape or bottle wrap 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®

#### **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®

**ALLERGY**  
ALERGIA

How can we help?  
¿Cómo podemos ayudar?

☎ 1-877-717-2824  
benadryl.com

NDC 50580-534-04

# Children's Benadryl®

**ALLERGY**  
ALERGIA

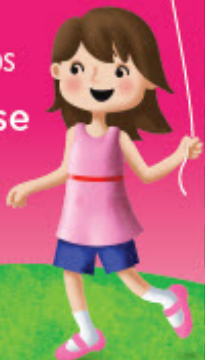
Diphenhydramine HCl/antihistamine  
12.5 mg / 5 mL oral solution

Difenhidramina ClH/antihistamínico  
12.5 mg/5 ml solución oral

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

**RELIEF OF:**  
ALIVIO DE:

- ✓ **Runny Nose**  
Secreción nasal
- ✓ **Sneezing**  
Estornudos
- ✓ **Itchy, Watery Eyes**  
Lagrimeo, picazón en los ojos
- ✓ **Itchy Throat or Nose**  
Picazón de garganta o nariz



Alcohol Free  
Sin alcohol

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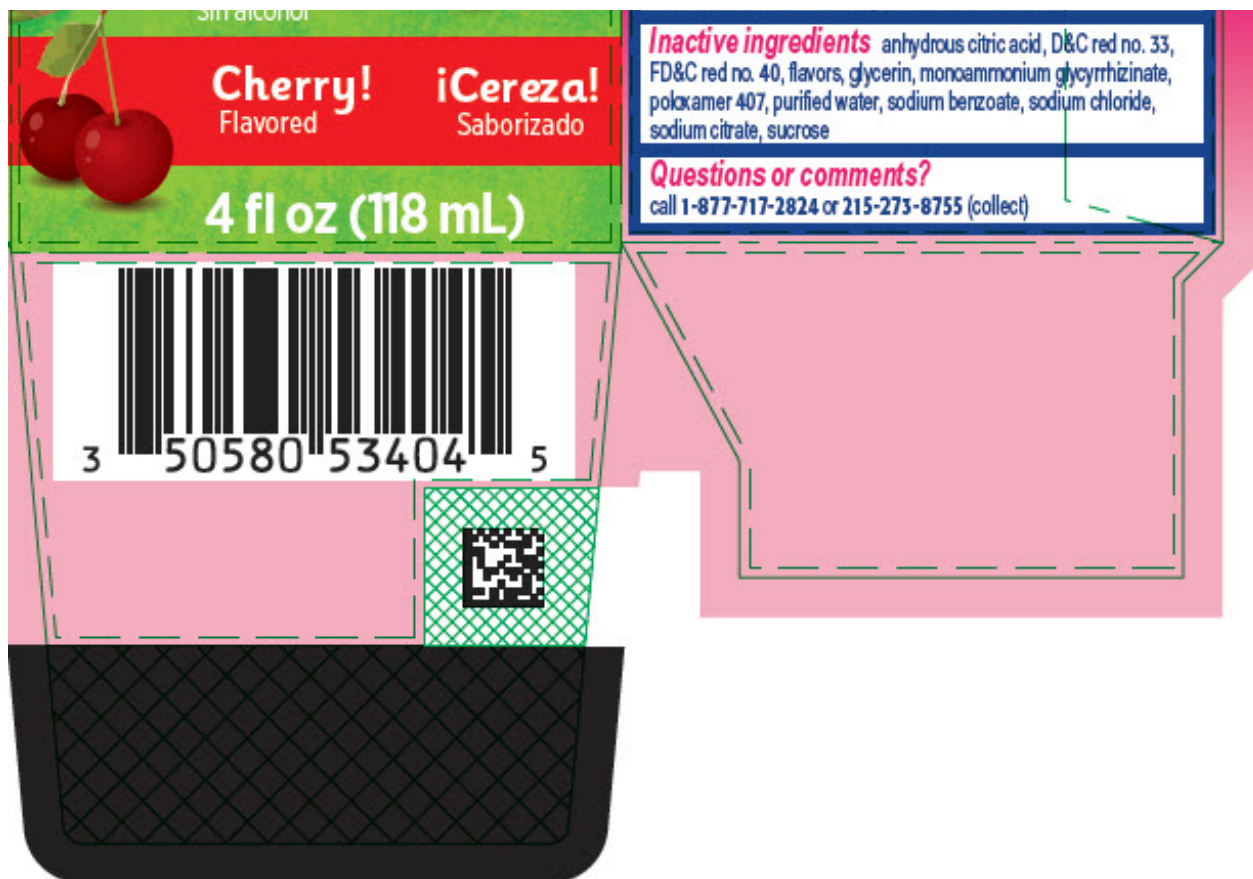
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**Ingrediente activo** **Acción terapéutica**

**(cada 5 ml)**

Difenhidramina ClH 12.5 mg.....Antihistamínico

**Indicaciones**

- alivio temporal de los siguientes 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 hacer 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)

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 la cinta del envase o el envoltorio de la botella que llevan impresas las palabras "Sealed For Your Safety"

**Ingredientes inactivos**

ácido cítrico anhidro, rojo N° 33 D&C, rojo N° 40 FD&C, saborizantes, glicerina, glicirizinato 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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**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

Ingredient Name	Basis of Strength	Strength
<b>Diphenhydramine hydrochloride</b> (UNII: TC2D6JAD40) (diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine hydrochloride	12.5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<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: TUF2IVW3M2)	
<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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	
3		1 in 1 CARTON		
3		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., McNeil Consumer Healthcare Division (878046358)

Revised: 11/2020

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division