

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

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[®]

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 ayudarlo?

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:
ALIVIA:

 **Runny Nose**
Secreción nasal

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✓ **Sneezing**
Estornudos

✓ **Itchy, Watery Eyes**
Lagrimeo, 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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-534
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)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLOXAMER 407 (UNII: TUF21VW3M2)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
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: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 - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024

Johnson & Johnson Consumer Inc.