

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.

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 "SAFETY SEAL®" 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 ayudarte?
☎ 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 HCl,
solución oral de 12.5 mg/5 mL, antihistamínico

4-6 Hours/Dose
Horas/Dosis

RELIEF OF:
ALIVIA:

- ✓ **Runny Nose**
Goteo nasal
- ✓ **Sneezing**
Estornudos
- ✓ **Itchy, Watery Eyes**
Lagrimo y picazón en los ojos
- ✓ **Itchy Throat or Nose**
Picazón en la nariz o la garganta



Alcohol Free
Sin Alcohol

Drug Facts

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Diphenhydramine HCl 12.5 mg.....	Antihistamine

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Other information

- each 5 mL contains: sodium 14 mg
- store between 20-25°C (68-77°F). Protect from light. Store in original carton until contents used.
- do not use if bottle wrap, or foil inner seal imprinted "SAFETY SEAL" is broken or missing

Inactive ingredients anhydrous citric acid, D&C red no. 33, FD&C



Cherry!
Flavored

Con sabor a
iCereza!

4 fl oz (118 mL)



LOT/EXP

red no. 40, flavors, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucrose

Questions or comments?

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Children's
Benadryl

ALLERGY
ALERGIA

Etiqueta de información

Ingrediente activo
(cada 5 ml)

Difenhidramina HCl 12.5 mg.....Antihistamínico

Acción terapéutica

Usos

■ alivia temporalmente estos síntomas por rinitis alérgica estacional u otras alergias del tracto respiratorio superior.

Etiqueta de información (continuación)

Indicaciones

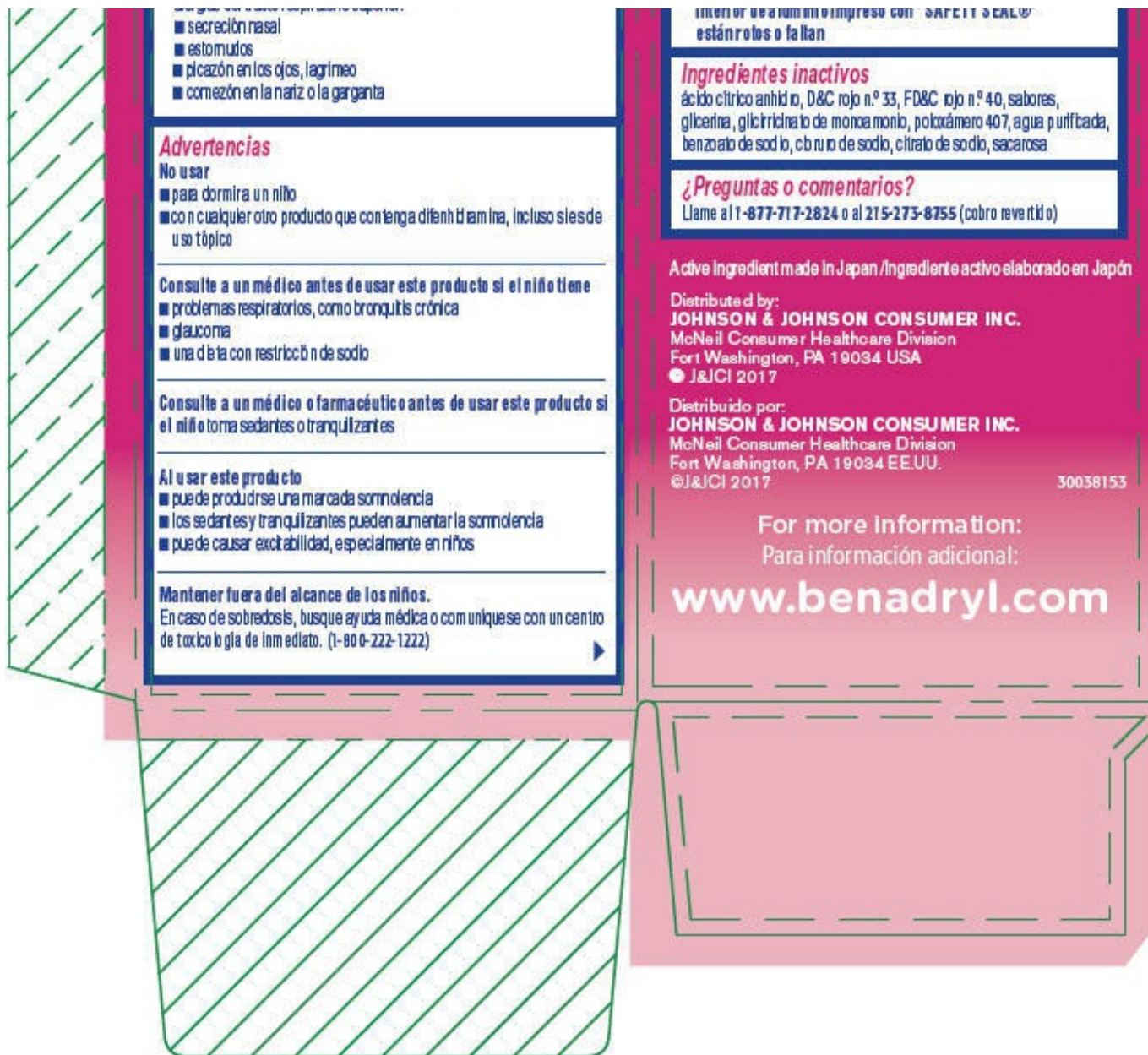
- buscar la dosis correcta en la tabla a continuación
- ml= mililitro
- tomar cada 4 a 6 horas, o según lo indicado por el médico
- no tomar más de 6 dosis en 24 horas

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

Atención: use solamente el vaso dosificador que se suministra adjunto, diseñado exclusivamente para usar con este producto. No usar ningún otro dispositivo de dosificación.

Otra información

- cada 5 ml contiene: sodio 14 mg
- almacenar entre 20-25°C (68-77°F). Proteger de la luz. Almacenar en la caja exterior hasta haber usado su contenido.
- no lo use si la envoltura de la botella o el sello



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: PDC6A3C00X)	
ammonium glycyrrhizate (UNII: 3VRD35U26C)	
poloxamer 407 (UNII: TUF2IVW3M2)	
water (UNII: 059QF0K00R)	
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	
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)