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)

Sneezing
Estornudos

Itchy, Watery Eyes
Lagrimeo, picazón en los ojos

Itchy Throat or Nose
Picazón de garganta o nariz

Alcohol Free
Sin alcohol

Cherry! Flavored
¡Cereza! Saborizado

4 fl oz (118 mL)

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LOT/EXP

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Children's Benadryl®
ALLERGY
ALERGIA

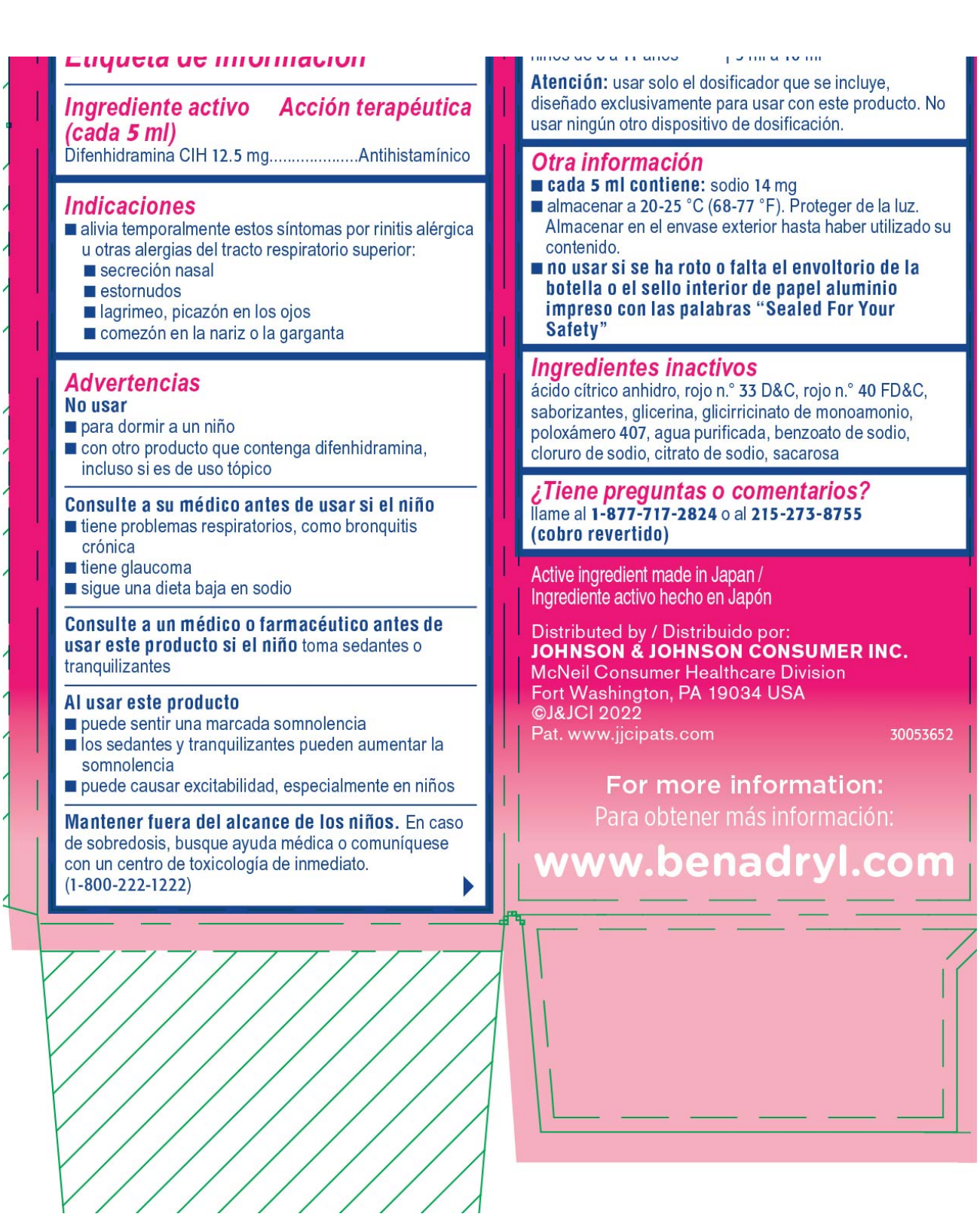
Etiqueta de información (continuación)

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



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: TUF2IVW3M2)	
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.