

CHILDRENS BENADRYL CHEWABLES- diphenhydramine hydrochloride tablet, chewable

Johnson & Johnson Consumer Inc.

Children's Benadryl[®] Chewables

Drug Facts

Active ingredient (in each chewable tablet)

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 you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- avoid alcohol drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a healthcare professional before use.

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
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

Age (yr)	Dose (chewable tablets)
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	1 to 2 chewable tablets (12.5 mg to 25 mg)
adults and children 12 years and over	2 to 4 chewable tablets (25 mg to 50 mg)

Other information

- store between 20-25°C (68-77°F). Avoid high humidity. Protect from light.
- **do not use if carton or blister unit is opened or broken/unsealed**
- see bottom panel for lot number and expiration date

Inactive ingredients

crospovidone, D&C red no. 30 aluminum lake, D&C red no. 7 calcium lake, dextrose excipient, ethylcellulose, FD&C blue no. 1 aluminum lake, flavors, gum arabic, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, sucralose, sugar spheres, tartaric acid

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-232-01

**Children's
Benadryl®**

ALLERGY

Diphenhydramine HCl/antihistamine 12.5 mg chewable tablets

Chewables

4-6 Hours/Dose

RELIEF OF:

- Runny Nose
- Sneezing
- Itchy, Watery Eyes
- Itchy Throat or Nose

20

Chewable Tablets

Grape!

Flavored

Tablets

Actual Size



How can we help?
¿Cómo podemos ayudarle?
1-877-717-2824
benadryl.com

NDC 50580-232-01



ALLERGY
ALERGIA

Diphenhydramine HCl/antihistamine 12.5 mg chewable tablets
Clorhidrato (hidrocloruro) de difenhidramina, tabletas masticables de 12.5 mg, antihistamínico

Chewables

Masticables

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

20
Chewable Tablets
Tabletas Masticables



Grape!
Flavored
Tablets

Tabletas
con sabor a
iUva!



Actual Size
Tamaño real



Información del medicamento (continuación)

Ingredientes inactivos: composición, laza de almirante D&C rojo n.º 7, acetato de aluminio, laza de almirante FD&C azul n.º 1, sales de goma arábiga, hidroxipropilcelulosa, estearato de magnesio, celulosa microcristalina, sacarosa, estearato de azúcar, ácido tartárico

¿Tiene alguna pregunta o comentario? llame al 1-877-717-2824 o 215-215-8755 (sólo por voz)

Important: Read all product information before using. Keep this box for important information.
Importante: Lea toda la información del producto antes de utilizarlo. Conserve el envase de este porque contiene información importante.

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312627

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 19084 USA
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Información del medicamento

Ingrediente activo (en cada tableta masticable) Propósito
Difenhidramina HCl 12.5 mg.....Antihistáminico

Usos

- alivio temporal de estos síntomas causados por la rinitis alérgica u otras alergias de las vías respiratorias superiores:
 - goteo nasal
 - estornudos
 - lagrimeo y picazón en los ojos
 - picazón en la nariz o garganta

Advertencias

- No lo use
 - para hacer que un niño duerma
 - con ningún otro producto que contenga difenhidramina, aunque sea de uso tópico en la piel

- Consulte con su médico antes de usar este producto si padece
- un problema respiratorio como enfisema o bronquitis crónica
 - glaucoma
 - dificultad para orinar debido al aumento del volumen de la glándula prostática

Consulte con un médico o farmacéutico antes de usar este producto si está tomando sedantes o tranquilizantes

- Al usar este producto
- puede presentarse una marcada somnolencia
 - evite las bebidas alcohólicas
 - el alcohol, los sedantes y los tranquilizantes pueden aumentar la somnolencia
 - tenga cuidado al conducir un vehículo a motor o al operar maquinarias
 - puede causar nerviosismo, particularmente en niños

En caso de estar embarazada o amamantando, consulte con un profesional del cuidado de la salud antes del uso. Manténgalo fuera del alcance de los niños. En caso de sobredosis, obtenga asistencia médica o comuníquese con un Centro de Control Toxicológico de Inmediata. (1-800-222-1222)

Indicaciones

- busque la dosis correcta en el cuadro siguiente
- tome el medicamento cada 4 a 6 horas, o según lo indique un médico
- no lo tome más de 6 veces en 24 horas

Edad (años)	Dosis (tabletas masticables)
niños menores de 2 años	no lo use
niños de 2 a 5 años	no lo use a menos que lo indique un médico
niños de 6 a 11 años	1 a 2 tabletas masticables (12,5 mg a 25 mg)
adultos y niños de 12 años y mayores	2 a 4 tabletas masticables (25 mg a 50 mg)

Información adicional

- conservar entre 20-25 °C (68-77 °F). Evitar la exposición a alta humedad. Proteger de la luz.
- no usar si la caja o el blíster está abierto o roto/sin protección
- ver el número de lote y la fecha de vencimiento en el panel inferior



CHILDRENS BENADRYL CHEWABLES

diphenhydramine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-232
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

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ACACIA (UNII: 5C5403N26O)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TARTARIC ACID (UNII: W4888I119H)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	purple	Score	no score
Shape	ROUND	Size	13mm
Flavor	GRAPE	Imprint Code	B
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-232-01	2 in 1 CARTON	07/11/2016	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/11/2016	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

