

CHILDRENS BENADRYL CHEWABLES- diphenhydramine hydrochloride tablet, chewable

Johnson & Johnson Consumer Inc.

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[®] 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

Children's
Benadryl[®]
ALLERGY
ALERGIA

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

NDC 50580-232-01

Children's
Benadryl[®]

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, DCL 0.17, 7, acetato de aluminio, etilalcol, laza de almirante, PBO, aculín, 1, sabores, goma arábiga, hidroxipropilcelulosa, estearato de magnesio, celulosa microcristalina, sacarosa, edulcorante de azúcar, ácido tartárico

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

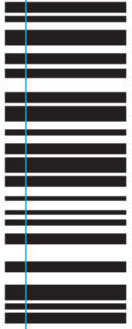
Important: Read all product information before using. Keep this box for important information.
Importante: Lea toda la información del producto antes de utilizarlo. Conserve el envase de este porque contiene información importante.

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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 a mamantando, 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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TARTARIC ACID (UNII: W4888I119H)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

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 final	part341	07/11/2016	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

