BENADRYL- diphenhydramine hydrochloride
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.

Benadryl

Drug Facts

Active ingredient (in each tablet)

Diphenhydramine HCl 25 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
- temporarily relieves these symptoms due to the common cold:
  - runny nose
  - sneezing

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 alcoholic 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 health 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

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

adults and children 12 years and over	1 to 2 tablets
children 6 to under 12 years	1 tablet
children under 6 years	do not use

Other information

- **each tablet contains:** calcium 15 mg
- store between 20-25°C (68-77°F). Protect from light.
- **do not use if carton is opened or carton tape and foil inner seal imprinted with "SAFETY SEAL®" are broken or missing**

Inactive ingredients

carnauba wax, croscarmellose sodium, D&C red no. 27 aluminum lake, dibasic calcium phosphate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

100+48 = 148

ULTRATABS®*
TABLETS

Benadryl®

WORKS WHEN YOU
NEED IT MOST™

*small tablet size

Distributed By:
Johnson & Johnson Consumer Inc.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034

Lot
Exp.

FPO

100 CT. BOTTLE

ON-THE-GO OR AT HOME

48 CT. BLISTER

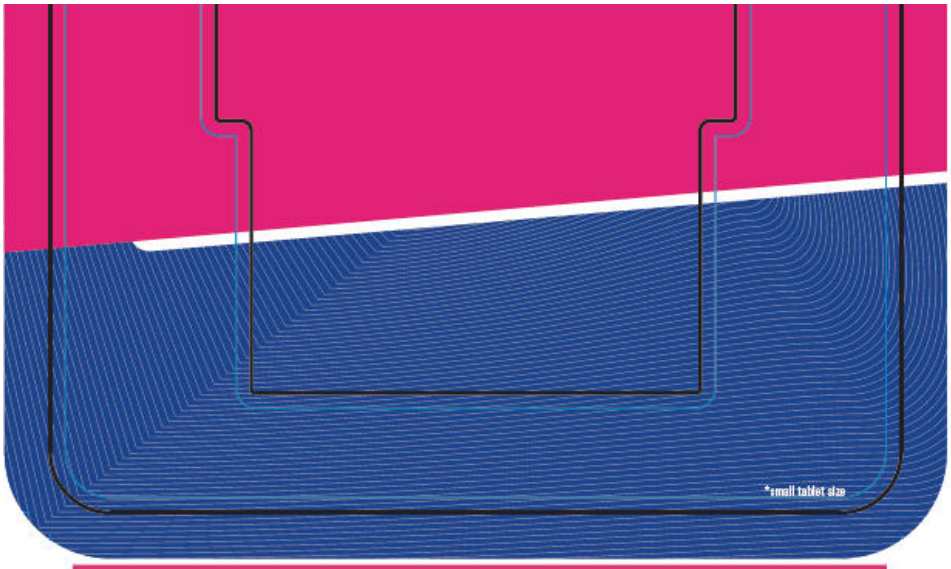
RELIEF YOU CAN TRUST FOR ALL SEASONS

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

100 + 48 = 148 ULTRATABS®* TABLETS

Benadryl®

WORKS WHEN YOU NEED IT MOST™



Benadryl® ALLERGY

EFFECTIVE ALLERGY RELIEF WHEN YOU NEED IT!®

For allergy tips and information, visit www.benadryl.com

Allergy Tips

Close the windows
Keep your windows closed to help keep allergens on the outside. If it gets warm, use an air-conditioner.

Change your clothes
If you've worn it outside, don't wear it inside. That way you avoid spreading allergens around your home.

Take off your shoes
Leave your shoes at the front door to avoid tracking dust and allergens into the home

NDC 50580-226-50

Benadryl® ALLERGY

Diphenhydramine HCl 25 mg
Antihistamine

ULTRATABS®*
*small tablet size

100 TABLETS

Important: Read all product information before using. Keep this box for important information.

Drug Facts

Active ingredient (in each tablet) — **Purpose**

Diphenhydramine HCl 25 mg ..... Antihistamine

Uses

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Drug Facts (continued)

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Questions or comments?

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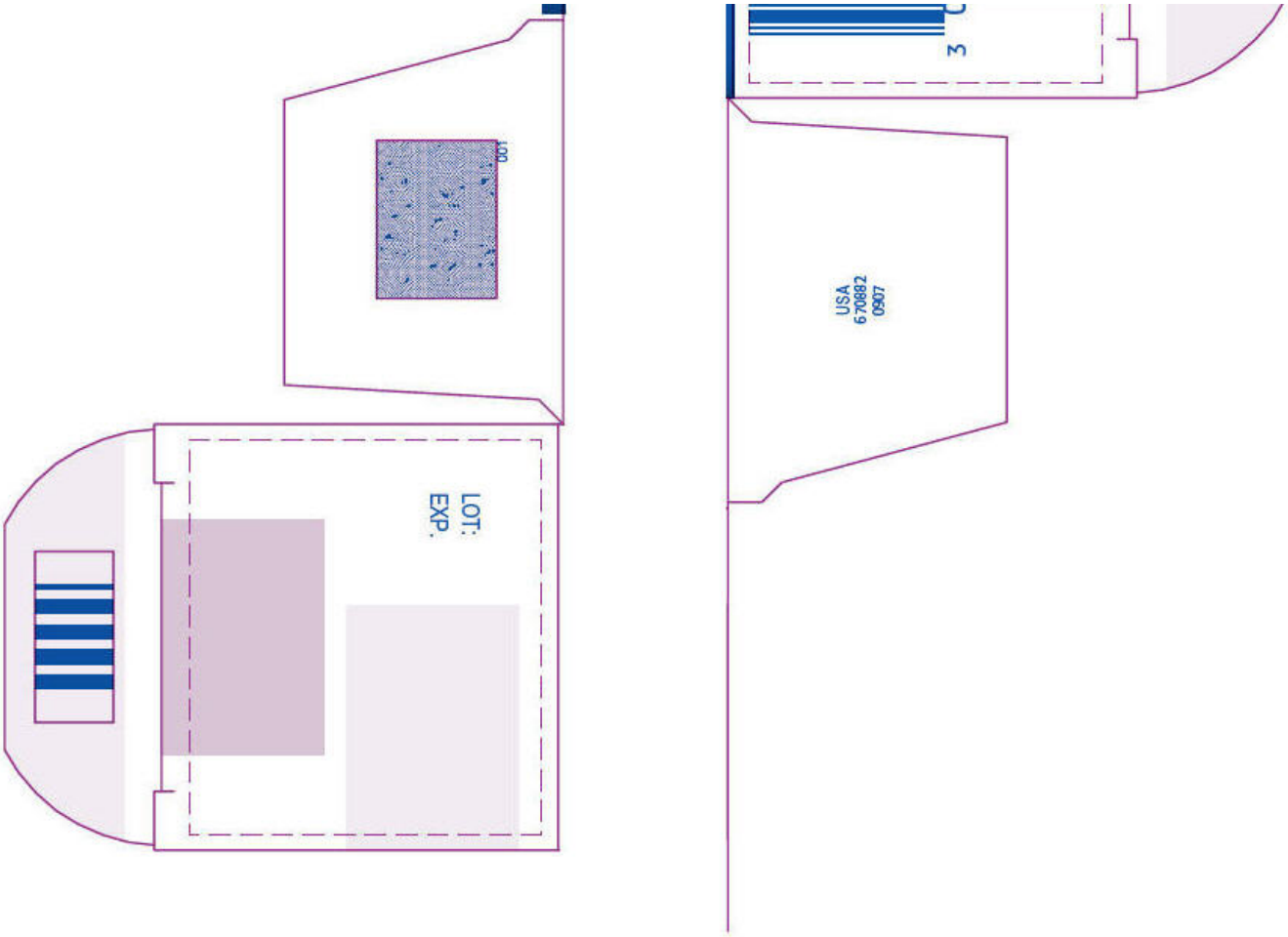
Active ingredient made in Japan

Distributed by: JOHNSON & JOHNSON CON McNeil Consumer Healthcare Division Fort Washington, PA 19034 USA



BENADRYL

diphenhydramine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-370

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50580-370-01	1 in 1 PACKAGE	06/12/2017	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	100
Part 2	4 BLISTER PACK	48

Part 1 of 2

BENADRYL

diphenhydramine hydrochloride tablet, film coated

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
diphenhydramine hydrochloride (UNII: TC2D6JAD40) (diphenhydramine - UNII:8GTS82S83M)	diphenhydramine hydrochloride	25 mg

Inactive Ingredients

Ingredient Name	Strength
carnauba wax (UNII: R12CBM0EIZ)	
croscarmellose sodium (UNII: M28OL1HH48)	
D&C red no. 27 aluminum lake (UNII: ZK64F7XSTX)	
dibasic calcium phosphate dihydrate (UNII: O7TSZ97GEP)	
hypromellose, unspecified (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
microcrystalline cellulose (UNII: OP1R32D61U)	
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	OVAL	**Size**	11mm
Flavor		**Imprint Code**	B;WL;25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		100 in 1 BOTTLE; 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	06/04/2012	

Part 2 of 2

BENADRYL

diphenhydramine hydrochloride tablet, film coated

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
diphenhydramine hydrochloride (UNII: TC2D6JAD40) (diphenhydramine - UNII:8GTS82S83M)	diphenhydramine hydrochloride	25 mg

Inactive Ingredients

Ingredient Name	Strength
carnauba wax (UNII: R12CBM0EIZ)	
croscarmellose sodium (UNII: M28OL1HH48)	
D&C red no. 27 aluminum lake (UNII: ZK64F7XSTX)	
dibasic calcium phosphate dihydrate (UNII: O7TSZ97GEP)	
hypromellose, unspecified (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
microcrystalline cellulose (UNII: OP1R32D61U)	
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	OVAL	**Size**	11mm
Flavor		**Imprint Code**	B;WL;25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 CARTON		
1		12 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	06/04/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	06/12/2017	

Labeler - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 12/2018 Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division