

BANOPHEN- diphenhydramine hcl capsule
Major Pharmaceuticals

0836-Major(100C/1000C)

Active Ingredient (in each banded capsule)

Diphenhydramine Hydrochloride 50 mg

Purpose

Antihistamine

Use

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies

- runny nose
- sneezing
- itchy, watery eyes
- itchy throat and nose
- Temporarily relieves these symptoms due to the common cold
 - runny nose
 - sneezing

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

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Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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.

Directions

- Take every 4-6 hours
- Do not take more than 6 doses in 24 hours

adults and children 12 years of age and over	Take 1 capsule (50 mg)
children under 12 years of age	ask a doctor, the proper dosage strength is not available in this package**

**Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.

Other Information

- Store in a dry place at 15° – 30°C (59° – 86°F).
- Do not use if either capsule band or imprinted safety seal under cap is broken or missing
- Protect from moisture
- Contains lactose

Inactive Ingredients

D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.

Questions?

Questions or comments? 1-800-231-4670

Distributed by: MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

www.majorpharmaceuticals.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Major

NDC 0904-5307-80

BENOPHEN

Complete Allergy Medication

Diphenhydramine HCl 50 mg

ANTIHISTAMINE

For the temporary relief from symptoms of:

- Upper Respiratory Allergies • Hay Fever

1000 CAPSULES

Each Capsule Individually Banded For Your Protection

THIS LARGE PACKAGE SIZE FOR DISPENSING PURPOSE ONLY

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Drug Facts

Active ingredient (in each banded capsule)
Diphenhydramine Hydrochloride 50 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 ■ in make a child sleep ■ with any other product containing diphenhydramine, even one used on skin
Ask a doctor before use if you have ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ 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 ■ do not take more than 6 doses in 24 hours
adults and children 12 years of age and over take 1 capsule (50 mg)
children under 12 years of age ask a doctor, the proper dosage strength is not available in this package**

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Other information ■ Store in a dry place at 15° - 30°C (59° - 86°F). ■ do not use if either capsule band or imprinted safety seal under cap is broken or missing ■ protect from moisture ■ contains lactose

Inactive ingredients D&C red #28; FD&C blue #1, FD&C red #40, gelatin, lactose and starch.

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Re-Order No. 008241



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BANOPHEN

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-5307
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength

D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	pink	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	CPC;836
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5307-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2009	01/31/2028
2	NDC:0904-5307-80	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2009	01/31/2028

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/02/2009	01/31/2028

Labeler - Major Pharmaceuticals (191427277)

Revised: 2/2026

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